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Attachment, Self and Social Knowledge, and Distress in Psychosis: A Research Portfolio

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Title of work: Attachment, self and social knowledge, and distress in psychosis

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This thesis is dedicated to Beryl, because the life you gave me the possibility of living was beyond even *my* wildest dreams.

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Research Portfolio Abstract

Background/Aims:

People with a diagnosis of psychosis often experience stigmatising social encounters. These social encounters may influence the beliefs people hold, as research suggests that people develop a range of processes in an attempt to interpret information about both themselves and others. The internalisation of negative stereotypes about psychosis is one process used to explain how people's beliefs are influenced. Cognitive models highlight the relationship between self and social knowledge and mood. How people process social information might therefore have an important role in pathways to distress in psychosis.

There is limited understanding of how different expressions of emotional distress might relate to the processing of social information. This research portfolio therefore has two aims. Firstly it aims to systematically review literature on the relationship between internalised stigma and distress for people with a schizophrenia spectrum diagnosis. It also aims to explore the relationship between attachment style, reflective functioning, personal beliefs about illness, and emotional distress in people who experience psychosis.

Method:

These two aims are addressed through two studies. The first study is reported in Chapter 1, where literature exploring the relationship between internalised stigma and measures of emotional distress was systematically reviewed. For this review, a search of electronic databases was conducted, included studies were assessed for quality, and results were outlined through a narrative synthesis. The empirical project reported in Chapter 2 employed a cross-sectional design to gather quantitative data from people who had a diagnosis related to psychosis. Mediation modelling was then used to explore cognitive appraisals as mediatory variables between attachment anxiety and

emotional distress whilst controlling for psychotic symptomatology as a potential confounding variable.

Results:

Thirty studies were included in the systematic review, with over half of these being cross-sectional in design. Systematic review findings indicate a significant association between internalised stigma and depression, however the association with other measures of distress was inconsistent. Limited data was therefore available regarding the utility of cognitive interventions focusing upon internalised stigma for improving symptoms of distress in psychosis. Results from the empirical study indicate associations between attachment anxiety, cognitive appraisals, and emotional distress but not reflective functioning. Personal beliefs about illness regarding shame and control were found to mediate the relationship between attachment anxiety and distress.

Conclusions:

When reviewed systematically the relationship between internalised stigma and distress remained unclear. This is due in part to methodological limitations of included studies which did not allow the exploration of whether these negative beliefs about the self in relation to others around them leads to distress. However, findings from the empirical study suggested personal beliefs about illness could influence the relationship between attachment and emotional distress. Future interventions focusing upon internalised stigma as a vehicle for improving symptoms of distress in psychosis might therefore target perceptions of shame and control whilst recognising a wider range of outcomes for distress.

Lay Summary

Different sources of distress have been identified for people living with psychosis. Whilst some people with psychosis find their symptoms distressing, others find having a diagnosis of psychosis distressing in itself. Research suggests that if people with psychosis experience stigma in social situations, this might change the way they think and feel about themselves. How people gather information about the world around them and use this to guide their attention, interpretations, and predictions about themselves and other people can differ. These individual differences in the way people make sense of social situations may change the level of distress a person with psychosis experiences. However there is a lack of research exploring how all these factors are related to each other.

A search of published research is presented in Chapter 1, where evidence is reviewed for a relationship between internalised stigma and distress for people with a schizophrenia spectrum diagnosis. Chapter 2 contains an exploration of the relationship between attachment style, the thoughts and feelings people use to make sense of themselves and others in social situations, and emotional distress in people who experience psychosis.

Results show that there was a relationship between internalised stigma and depression, but evidence for a relationship with other forms of distress was inconsistent. These inconsistencies made it difficult to ascertain whether one factor influenced another, or the relationship was bi-directional. Interventions designed to reduce levels of internalised stigma by focusing on thoughts did not appear to be effective in reducing distress for people with psychosis. However findings also showed that some types of thought exerted a greater influence upon the relationship between attachment and distress than others. It is therefore recommended that future interventions seeking to reduce distress in people with psychosis focus on negative thoughts about the self in relation to others.

Chapter 1: Systematic Review[1]

1.1 Title Page[2]

The relationship between internalised stigma and distress experienced by people with a schizophrenia-spectrum diagnosis: A systematic review

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This review was completed as part of a Doctorate in Clinical Psychology, undertaken with the University of Edinburgh and NHS Forth Valley.

[1]Produced according to author information and submission guidelines for Clinical Psychology Review (see Appendix A). Tables and figures however, are inserted alongside corresponding text as per recommendations for thesis submission.

[2]Numbering of titles is included throughout for continuity of thesis portfolio, but would not be included for journal submission.

1.2 Abstract

Individuals with a schizophrenia-spectrum diagnosis are likely to experience high levels of internalised stigma. Cognitive models highlight the relationship between self and social knowledge, and mood. The nature of association between internalised stigma, as one aspect of an individual's appraisal of self and social knowledge, and distress therefore warrants further investigation. A systematic review was conducted to investigate the relationship between internalised stigma and distress for people with a schizophrenia spectrum diagnosis. The search identified 30 studies published between 2002 and 2019. Study findings indicate a significant association between internalised stigma and depression. However, associations between internalised stigma and other measures of distress such as anxiety and shame were found to be inconsistent. Limited data were available about the utility of interventions which focused upon internalised stigma for improving symptoms of distress. Overall, there was insufficient evidence to indicate the relationship directionality between internalised stigma and distress. One explanation for this finding is the influence of variables such as insight. Future research should allow for the greater expression of distress, with emphasis on potential directionality of this association between self and social knowledge, whilst controlling for potential confounding variables.

Keywords: schizophrenia; psychosis; internalised stigma; distress

Highlights:

- Internalised stigma was related to depression.
- Internalised stigma did not consistently predict other measures of emotional distress.
- Few interventions for internalised stigma focused upon improving emotional distress

1.3 Introduction

Significant levels of stigma around psychosis continue to exist in society, with Henderson et al. (2012) finding 87% of respondents reporting experiences such as being avoided or treated unfairly by someone who knew about their diagnosis. Research investigating the impact of these social experiences has indicated that stigmatizing social encounters may influence both the behaviour a person exhibits and the beliefs they hold (Mestdagh & Hansen, 2014).

Corrigan and Watson (2002) differentiated between the concepts of public stigma and self-stigma by comparing and contrasting their mutual components of stereotype, prejudice, and discrimination. Corrigan et al. (2010) furthered this work and explained that the term 'internalised stigma' can be used to describe the process of an individual becoming aware of a negative stereotype, agreeing with it, and then applying it to themselves. An individual experiencing internalising stigma might therefore develop a negative belief about themselves possessing a particular character weakness (stereotype), experience a negative emotional reaction such as lowered self-esteem through agreement with the belief (prejudice), and then fail to pursue employment as a behavioural response to this prejudice (discrimination). As the terms self-stigma and internalised stigma are often used interchangeably within literature, this review will continue with the term internalised stigma (IS) for the purposes of clarity.

Research has sought to better understand the impact of IS for people who live with a schizophrenia spectrum diagnosis. Systematic reviews and meta-analyses which include studies representing participants with a schizophrenia spectrum diagnosis have consistently identified a robust relationship between IS and a range of psychosocial variables such as self-esteem and quality of life (Livingston & Boyd, 2010), hope and empowerment (Gerlinger et al., 2013), withdrawal and social isolation (Oliveria, Estives, & Carvalho, 2015).

As such, recent researchers have increasingly focused their attention upon the development of interventions to reduce IS.

A number of different outcomes have been evaluated within research examining the efficacy of IS interventions. This range of outcomes may reflect the different theoretical models which researchers have implemented in attempts to develop increasingly targeted interventions. Earlier studies such as Knight et al. (2006) reported upon the impact of their CBT intervention for IS upon positive and negative symptoms of schizophrenia. Whilst other earlier intervention studies focused for example upon IS with self efficacy as secondary outcome measures (Fung, Tsang, & Cheung, 2011), this appears to be largely driven by a desire to improve treatment adherence. Later interventions have moved towards measuring self esteem and quality of life (e.g. Hansson & Yanos, 2016; Yanos et al., 2019).

Research has indicated that existing interventions show no significant impact on IS as a primary outcome measure (e.g. Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002; Morrison et al., 2016; Russinova et al., 2014). However, studies report a significant positive impact on secondary outcomes such as hopelessness (Yanos, Roe, & Lysaker, 2011) and self-esteem (Morrison et al., 2016). Furthermore, through the reviewing of IS interventions and their change mechanisms, Yanos, Lucksted, Drapalski, Roe, and Lysaker (2015) suggested that cognitive challenging was one of the most important elements of an intervention. This is supported by evidence which suggests that the activation of automatic shame thoughts can be a risk factor for IS through discrimination being perceived as legitimate (Rusch, Todd, Bodenhausen, Olschewski, & Corrigan, 2010). Despite the small effect sizes observed thus far, progress in developing an effective intervention has been considered positive when viewed in light of sample sizes employed, and the necessity to develop more targeted interventions (Wood, Byrne, Varese, & Morrison, 2016).

During the development of these increasingly targeted interventions, researchers have drawn upon a number of different models to better understand the psychological processes involved in IS. Link and Phelan's (2001) model drew upon social cognitive conceptualisations of stigma which emphasises the emotional distress and subsequent behavioural adaptations for a person who develops appraisals that they will be rejected due to experiencing social disapproval for what they perceive be their undesirable characteristic. Drawing increasingly upon models which emphasise emotional distress may have laid ground work for a later shift towards intervention studies investigating affect-based changes as secondary outcomes alongside changes in psychotic symptomatology.

Link and Phelan's (2001) model identifies how labelling, for example in being given a mental health diagnosis, can lead to people being separated socially in the minds of others. Negative stereotypes about people with mental health difficulties are suggested to create a sense of perceived difference which then results in status loss and subsequent experiences of discrimination (Link & Phelan, 2001). However, Link and Phelan's (2001) model lacks specificity to schizophrenia-spectrum diagnoses as it was developed for broader application to the experiences of those with severe mental illness.

People may be impacted differently by IS following diagnosis due to the differences in media portrayals and illness course of psychiatric diagnoses (Ross, Morgan, Jorm, & Reavley, 2019). Literature suggests that some interventions are better suited for people who have experienced their first psychotic episode whilst other interventions might be more relevant for whom the course of illness is more chronic (Yanos, Lucksted, Drapalski, Roe, & Lysaker, 2015). Systematic review (Yanos, Lucksted, Drapalski, Roe, & Lysaker, 2015) of these different interventions identified that a range of mechanisms of action had been targeted (e.g. psycho-education, cognitive restructuring, social skills training, narrative enhancement) thus supporting the need for a model of IS specific to schizophrenia-spectrum diagnoses.

Birchwood et al. (2007) address this need by developing a model which was specific to the experience of those diagnosed with psychosis. This model suggested that a person might respond with distress following the development of beliefs of holding a shameful attribute and appraisals that others will reject them (Birchwood et al., 2007). Rather than drawing upon the stigma theory proposed by Corrigan and Watson (2002), Birchwood et al. (2007) based their model on Clark and Wells' (1995) cognitive behavioural model of social anxiety. This allowed Birchwood et al. (2007) to extend Link and Phelan's (2001) theory specifically for people with psychosis by providing a clearer mechanism by which distress might develop and be maintained. Birchwood et al.'s (2007) model therefore suggested that IS may lead an individual to fear negative evaluation or rejection by others. These fears are then hypothesised to result in an individual becoming hyper-vigilant to their performance in social situations with shame-based beliefs about the self increasing anxiety levels (Birchwood et al., 2007).

Birchwood et al.'s (2007) model proposes a level of hyper-vigilance and fear of negative evaluation which would suggest that people with higher levels of insight would be related to higher levels of IS thus leading to poorer outcomes. This association between insight, IS and distress is supported by research (Cavelti, Rusch, & Vauth, 2014). An increasing evidence base for the theorised association between IS and distress may have provided support for researchers seeking to investigate potential secondary outcomes for their interventions.

However Birchwood et al.'s (2007) model appears to provide a clearer explanation for the development and maintenance of social anxiety in psychosis, rather than IS and the many other emotional reactions related to IS as described in literature. Furthermore, Birchwood et al.'s (2007) does not account for the different experiences which may be encountered by people in different stages of illness. Stage of illness appears to be key in developing an

effective intervention for IS (Yanos, Lucksted, Drapalski, Roe, & Lysaker, 2015) and differential exposure to stigma triggers may therefore be important within the development of cognitions.

Wood, Byrne, and Morrison (2017) therefore proposed a model which integrates elements of existing models of stigma, social theory, and Morrison's (2001) cognitive model of psychosis. The model (see Figure 1) extends the key aspects of cognitive, behavioural, and emotional processes identified within Morrison's (2001) model, and suggests how relationships between those components might contribute to the development and maintenance of IS (Wood, Byrne, & Morrison, 2017).

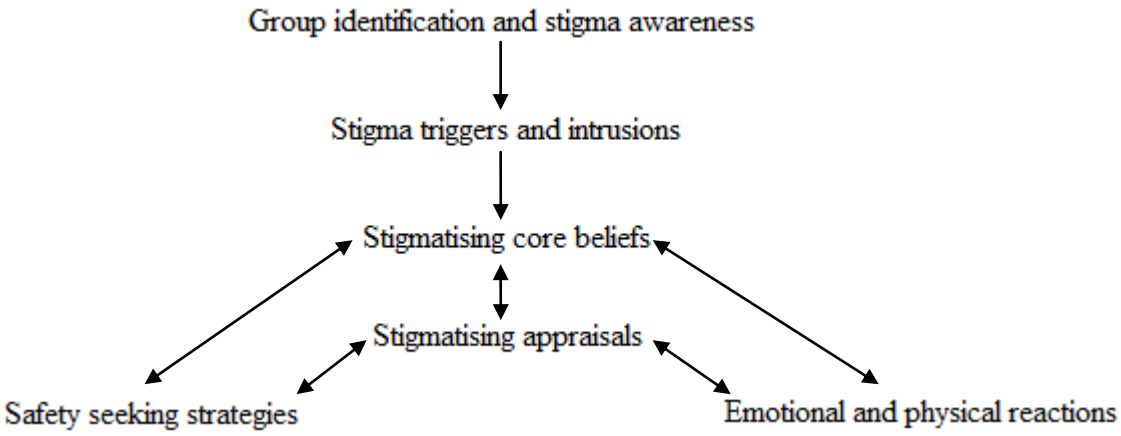

Figure 1. Model of internalised stigma in psychosis (from Wood et al., 2017)

The development of Wood et al.'s (2017) model appears to acknowledge that to design increasingly targeted interventions for IS, a more nuanced model was required to facilitate greater understanding of the appraisal-affect mechanism. Recognising the impact of stigma triggers and intrusions allows for a greater understanding of differences between IS cognitions and emotional distress for people with the same schizophrenia spectrum diagnosis at different stages of illness. Wood, Byrne, and Morrison (2017) argue that when applying Corrigan and Watson's (2002) theory of IS, stigmatising appraisals can lead to a range of complex emotional reactions such as social anxiety, shame/depression, and anger as three key emotional

responses. Whilst each of these three emotional responses has been described through qualitative interview with people who experience psychosis (Wood et al., 2015), quantitative evidence for this key component is also growing (e.g. Birchwood et al., 2007; Collett, Pugh, Waite, & Freeman, 2016; Lien et al., 2018; Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002; Lysaker, Yanos, Outcalt, & Roe, 2010).

Livingston and Boyd's (2010) review highlights the need for a greater understanding of the relationship between IS and other psychosocial variables. Similarly, Wood, Byrne, Varese, and Morrison (2016) recommend an increased emphasis on outcomes of psychological distress when evaluating interventions for IS. The importance of attending to the relationship between IS and distress becomes clear when viewed as a key component of an integrative cognitive model of IS in psychosis which has yet to be fully explored. This paper will therefore review studies investigating the relationship between IS appraisals of the self in relation to others and distress experienced by people with a schizophrenia spectrum diagnosis. Through this review, it is hoped that evidence will be evaluated for a key component of Wood, Byrne, and Morrison's (2017) cognitive model.

1.4 Method

1.4.1 Definition of terms

The broader concept of self and social knowledge found within cognitive models was narrowed to focus upon internalised stigma for the purposes of this review. Within the present review, internalised stigma is defined as the cognitions which result from an individual applying negative stereotypes about their schizophrenia spectrum diagnosis to themselves (Corrigan et al., 2010). Internalised stigma has therefore been operationalised in terms of how much an individual agrees or disagrees with statements which commonly include cognitions relating to stereotype endorsement, perceived

discrimination, alienation, social withdrawal, and stigma resistance (Ritsher, Otilingham, & Grajales, 2003).

Distress was defined as affective symptoms which co-exist alongside the positive and negative symptoms experienced by an individual diagnosed with a schizophrenia spectrum disorder. This is in line with Birchwood's (2003) proposed pathways to emotional dysfunction since the potential for distress is recognised as both intrinsic to, and a reaction to the diagnosis of, psychosis. For the purpose of this review, associations are explored in relation to emotional distress and cognitive appraisals of diagnosis with a schizophrenia spectrum disorder. Research has highlighted depression, anxiety, anger, social anxiety, and shame as particularly prevalent in people who experience psychosis (Birchwood et al., 2007; Oliveria, Estives, & Carvalho, 2015; Rusch, Todd, Bodenhausen, Olschewski, & Corrigan, 2010). Measures for these expressions of distress have therefore been considered in this review.

1.4.2 Search procedure

A search was conducted through the electronic databases of PsychINFO, Embase, MEDLINE, ASSIA, and CINAHL. The Cochrane Central Register of Controlled Trials (CENTRAL) was also examined to identify any further studies soon to be published. Searches used the following keywords: (schizophreni* OR psychosis OR psychotic OR paranoid OR hallucination OR delusion) AND (stigma OR belief OR appraisal OR attitude OR schema) AND (distress OR depression OR anxiety OR anger OR shame OR guilt). After removing duplicates, the titles and abstracts of articles were screened, with full texts sourced for relevant studies. For cases where inclusion of an article was uncertain, the methods and results sections were also reviewed. References lists from included studies were examined for any additional articles.

1.4.3 Inclusion and exclusion criteria

Studies were included if they were in English language, with a sample of adults aged 16-65 years, where participants meet the criteria for a primary schizophrenia spectrum diagnosis (schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, psychotic disorder not otherwise specified) or first episode psychosis. Other criteria for inclusion were studies which were peer-reviewed, used a quantitative methodology, and examined validated measures of internalised stigma and distress. Exclusion criteria required that studies had included no more than 50% of participants with other psychiatric diagnoses or subclinical (e.g. high risk or prodromal) stages. Grey literature (e.g. dissertations, conference abstracts) was also excluded. Studies were reviewed up to and including July in 2019.

1.5 Results

After applying the above criteria, the total number of articles included in this review was 30 (see Figure 2). Given the quantitative nature of this review and the inclusion of intervention studies, the possibility of a meta-analysis was considered. Despite this initial possibility, evaluation of the included study characteristics led to concerns over the risk of bias and potential for a meta-analysis to produce misleading results. These concerns were based upon findings of significant clinical diversity in the sample group, interventions delivered, and construct of IS in outcomes which were to be compared.

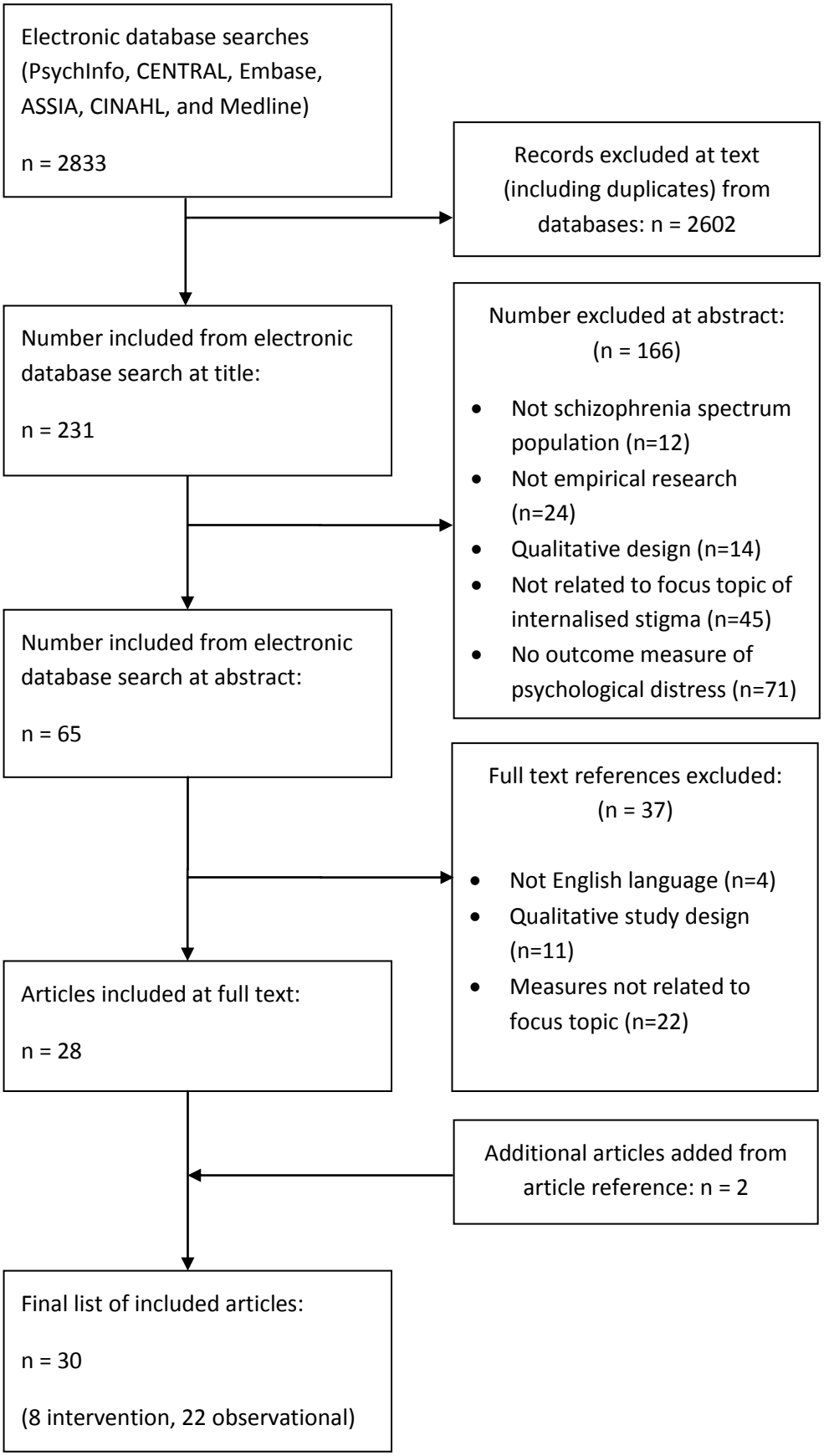

Figure 2. PRISMA flow diagram of search strategy

1.5.1 Overview of the study characteristics

Studies took place in a range of locations including Europe, North America, and Asia. Over half the studies (*n* = 16) used a cross sectional design. While eight intervention studies were identified, only six of these were RCTs. Sample size ranged from *n* = 21 to *n* = 927.

The majority of studies (*n* = 19) included participants exclusively with a schizophrenia spectrum diagnosis, or included participants with a schizophrenia spectrum diagnosis alongside other severe and enduring mental health diagnoses (*n* = 5). However a small number (*n* = 3) focused upon first episode psychosis only.

Table 1. Demographic and methodological features of included studies (presented chronologically)

Intervention Studies

Author, date and location	Method	Measurement	Schizophrenia related diagnosis n (%)	Sample *n* Female (%)	Drop out n (%)	Age (years), Mean (SD)
Link et al. (2002) USA	RCT 8 week social stigma psycho-education group vs control	Self-report	S, 36% NAP, 14%	*n* = 88 Female = 39%	Drop out: 38%	40.9 (NR)
Knight et al. (2006) UK	Time series 7 week CBT group vs waiting list control	Self-report	SSD, 100%	*n* = 21 Female = 48%	Drop out: 10%	39.3 (8.8)
Lysaker et al. (2010) USA	Cohort Baseline and 5 month follow-up, <20h per week vocational rehabilitation	Self-report	SSD, 100%	*n* = 78 Female = 15%	Drop out: NR	46.7 (8.7)
Russinova et al. (2014) USA	RCT 10 week peer-led photovoice psycho-education group vs waiting list control	Self-report	S, 34% B, 33% D, 25% Other, 7%	*n* = 82 Female = 68%	Drop out: 5%	18+ With 68% aged 40+
Morrison et al. (2016) UK	RCT 12 individual sessions of CT vs TAU.	Self-report	FEP, 47% S, 34% B, 14% SA, 3%	*n* = 29 Female = 21%	Drop out: 7%	34.3 (13.3)
de Jong et al. (2018) The Netherlands	RCT 40 individual sessions of MERIT vs TAU	Self-report	S, 67% SA, 33%	*n* = 70 Female = 30%	Drop out: 49%	40.0 (11.3)
Ho et al. (2018) Hong Kong	RCT 1 year extended early intervention vs TAU 2 year step down intervention	Observer rated by interview	FEP, 100%	*n* = 160 Female = 47%	Drop out: 15%	23.0 (3.3)
Wood et el. (2018) UK	RCT 2 hour CBT session vs SPE intervention	Self-report	SSD, 100%	*n* = 30 Female = 23%	Drop out: 27%	33.6 (12.9)

Observational studies

Author, date and location	Method	Measurement	Schizophrenia related diagnosis n (%)	Sample *n* Female (%)	Drop out n (%)	Age (years), Mean (SD)
Ritsher & Phelan (2004) USA	Cross sectional Baseline and 4-month follow up	Self-report	SSD, 100%	*n* = 82 Female = 9%	Drop out: 35%	51.0 (10.0)
Birchwood et al. (2006) UK	Cross sectional Between groups comparison of Social anxiety vs No social anxiety	Observer rated by interview	FEP, 100%	*n* = 79 Female = 23%	Drop out: NR	NR
Vauth et al. (2007) Germany	Cross sectional	Self-report	SSD, 100%	*n* = 172 Female = 40%	Drop out: NR	39.6 (11.0)
Kleim et al. (2008) Germany	Cross sectional	Self-report	S, 100%	*n* = 127 Female = 44%	Drop out: NR	38.9 (10.7)
Norman et al. (2011) Canada	Cross sectional	Observer-rated mood scales blind to self-rated outcomes.	FEP, 100%	*n* = 102 Female = 29%	Drop out: NR	26.9 (7.4)
Sibitz et al. (2011) Austria	Cross sectional	Self-report	SSD, 100%	*n* = 172 Female = 46%	Drop out: 14%	37.3 (11.9)
Ben-Zeev et al. (2012) USA	Longitudinal 6 x assessments daily over 1 week period	Self-report	SSD, 100%	*n* = 24 Female = 29%	Drop out: 0%	44.9 (9.3)
Michail & Birchwood (2013) UK	Cross-sectional Comparison of four groups	Self-report	FEP 44% FEP/SAD 15% SAD 23% HC 18%	*n* = 135 Female = 47%	Drop out: NR	25.2 (4.9)
Cavelti et al. (2014) Switzerland	Longitudinal Baseline and 1 year follow-up with no intervention	Self-report and observer rated	SSD, 100%	*n* = 133 Female = 35%	Drop out: 24%	44.5 (11.9)

Schrank et al. (2014) Austria	Cross sectional	Self-report	SSD, 100%	*n* = 284 Female = 42%	Drop out: NR	39.9 (12.6)
Lien et al. (2015) Taiwan	Cross sectional	Self-report	S, 31% SA, 19% B, 14% MD, 36%	*n* = 170 Female = 50%	Drop out: 6%	43.6 (11.8)
Valiente et al. (2015) Spain	Cross sectional Focus on persecutory beliefs	Self-report	SSD, 100%	*n* = 51 Female = 43%	Drop out: 8%	31.0 (8.4)
Yoo et al. (2015) Korea	Cross sectional	Self-report	SSD, 100%	*n* = 87 Female = 41%	Drop out: NR	34.5 (9.8)
Boyd et al. (2016) USA	Longitudinal Baseline, 3-month, and 6-month follow up	Self-report	SSD, 100%	*n* = 927 Female = 6%	Drop out: 17%	49.6 (8.5)
Collett et al. (2016) UK	Cross sectional Between groups comparison of persecutory delusion vs non-clinical control	Self-report	NAP, 50% Control, 50%	*n* = 42 Female = 52%	Drop out: NR	43.8 (12.2)
Espinosa et al. (2016) Spain	Cross sectional	Self-report	SSD, 100%	*n* = 50 Female = 39%	Drop out: NR	32.5 (9.6)
Murri et al. (2016) Italy	Cross sectional	Self-report and observer rated	S, 100%	*n* = 89 Female = 30%	Drop out: NR	42.2 (10.8)
Vrbova et al. (2017) Czech Republic	Cross sectional Between groups comparison of SSD vs SSD with SP	Self-report	SSD, 69% SSD/SP, 31%	*n* = 61 Female = 51%	Drop out: 13%	35.6 (9.6)
Lagger et al. (2018) Austria	Longitudinal Baseline, 3-month, and 6-month follow up	Self-report	SSD, 100%	*n* = 284 Female = 35%	Drop out: 65%	39.6 (11.2)
Lien et al. (2018) Taiwan	Cross sectional	Self-report	SSD, 100%	*n* = 190 Female = 45%	Drop out: 11%	44.4 (10.1)

Morgades-Bamba et al. (2019) Spain	Cross sectional	Self-report	SSD, 100%	*n* = 216 Female = 28%	Drop out: NR	43.9 (9.3)
Pellet et al. (2019) Switzerland	Longitudinal Baseline, 2-month, and 6-month follow up	Observer rated by interview	SSD, 100%	*n* = 80 Female = 39%	Drop out: 11%	39.9 (10.9)

B Bi-polar, CT Cognitive therapy, D Depression, FEP First episode psychosis, HC Healthy control, MD Mood disorders, MERIT Metacognitive Reflection and Insight Therapy, NAP Non-affective psychosis, NR Not recorded, RCT Randomised control trial, S Schizophrenia, SA Schizoaffective disorder, SP Social Phobia, SPE social stigma and psycho-education, SSD DSM-IV Schizophrenia spectrum disorder, TAU Treatment as usual

1.5.2 Quality assessment

Intervention studies were assessed using the Quality assessment tool for quantitative studies (EPHPP; Effective Public Health Practice Project, 1998). Cross sectional and longitudinal studies were assessed using an amended version of the Quality Assessment Tool for Observational Cohort and Cross Sectional Studies (QAT; National Institute for Health, 2017). By using the QAT, it was possible to further differentiate the quality as piloting of the EPHPP indicated a floor effect. Quality assessments were completed by the author, with 30% subjected to independent secondary review by a peer. The initial inter-rater reliability was moderate (k = 0.65) due to differences in the identification of confounding variables, however any discrepancies in ratings were resolved during early discussion. Quality assessment ratings are outlined in Table 2.

For the experimental studies, global ratings of bias were mixed which reflected the strong methodology of RCTs in comparison to intervention studies (Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002; Knight, Wykes, & Hayward, 2006) which did not use blinding procedures or control for confounding variables. Only one study (Morrison et al., 2016) rated strongly in the selection bias category, as the other studies had not sampled from a variety of services. It is of note that studies varied in their controlling of confounding variables and explicit descriptions of blinding procedures for group allocation.

There was greater variance in the global ratings of bias for the cross sectional and longitudinal studies than for the experimental studies. This variety in global ratings may be understood in the context of; two studies which did not clearly state their research question or objective, six studies which did not describe any statistical adjustment for confounding variables, and four of the five longitudinal studies which experienced significant losses to follow up. Furthermore, only three studies gave a sample size justification or power description.

Table 4.1 Effective Public Health Practice Project (EPHPP) assessment of bias for intervention studies

Study	Selection bias	Study design	Confounders	Blinding	Data collection methods	Withdrawal/ dropouts	Global rating
Link et al. (2002)	Moderate	Strong	Weak	Weak	Strong	Moderate	Weak
Knight et al. (2006)	Moderate	Weak	Weak	Weak	Strong	Strong	Weak
Lysaker et al. (2010)	Moderate	Weak	Moderate	Moderate	Strong	Moderate	Moderate
Russinova et al. (2014)	Moderate	Strong	Strong	Moderate	Strong	Strong	Strong
Morrison et al. (2016)	Strong	Strong	Strong	Strong	Strong	Strong	Strong
de Jong et al. (2018)	Moderate	Strong	Strong	Strong	Moderate	Moderate	Strong
Ho et al. (2018)	Moderate	Strong	Strong	Weak	Strong	Moderate	Moderate
Wood et el. (2018)	Moderate	Strong	Moderate	Moderate	Moderate	Strong	Strong

Table 4.2 National Institute of Health (NIH) assessment of bias for observational studies

Study	Objective	Population	Sample size	Loss to follow-up	Timeframe	Independent variables	Dependent variables	Confounding variables	Global rating
Ritsher & Phelan (2004)	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Good
Birchwood et al. (2006)	Yes	Yes	No	NA	NA	Yes	Yes	Yes	Good
Vauth et al. (2007)	Yes	Yes	Yes	NA	NA	Yes	Yes	No	Fair
Kleim et al. (2008)	Yes	Yes	No	NA	NA	Yes	Yes	No	Fair
Norman et al. (2011)	Yes	Yes	No	NA	NA	No	No	Yes	Poor
Sibitz et al. (2011)	Yes	Yes	No	NA	NA	Yes	Yes	Yes	Good
Ben-Zeev et al. (2012)	No	No	No	No	Yes	Yes	No	No	Poor
Michail & Birchwood (2013)	Yes	Yes	No	NA	NA	Yes	Yes	Yes	Good
Cavelti et al. (2014)	Yes	Yes	No	Yes	Yes	No	No	Yes	Fair
Schrank et al. (2014)	Yes	Yes	No	NA	NA	Yes	Yes	No	Good
Lien et al. (2015)	No	Yes	Yes	NA	NA	Yes	Yes	No	Good
Valiente et al.(2015)	Yes	Yes	No	NA	NA	Yes	Yes	No	Good
Yoo et al. (2015)	Yes	Yes	No	NA	NA	No	No	Yes	Poor
Boyd et al. (2016)	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Fair
Collett et al. (2016)	Yes	Yes	Yes	NA	NA	Yes	Yes	Yes	Good

Espinosa et al. (2016)	Yes	Yes	No	NA	NA	Yes	Yes	No	Fair
Murri et al. (2016)	Yes	Yes	No	NA	NA	No	No	Yes	Fair
Vrbova et al. (2017)	Yes	Yes	No	NA	NA	No	Yes	Yes	Fair
Lagger et al. (2018)	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Good
Lien et al. (2018)	Yes	Yes	No	NA	NA	Yes	Yes	Yes	Good
Morgades-Bamba et al. (2019)	Yes	Yes	No	NA	NA	Yes	Yes	Yes	Good
Pellet et al. (2019)	Yes	Yes	No	Yes	Yes	No	No	Yes	Fair
Yes - Key concept considered, No - Key concept not adequately considered, NA - Not applicable									

1.5.3 Overview of the interventions for internalised stigma

The interventions described within included studies varied, with the four RCTs from 2016 onwards (Ho et al., 2018; de Jong et al., 2018; Morrison et al., 2016; Wood, Byrne, Enache, & Morrison, 2018) offering an individual intervention format rather than the group format preferred in earlier studies (Knight, Wykes, & Hayward, 2006; Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002; Lysaker, Yanos, Outcalt, & Roe, 2010; Russinova et al., 2014). Interventions for internalised stigma, with secondary distress outcomes reported, varied.

Of the experimental studies reviewed, 50% drew upon cognitive models for their intervention (de Jong et al., 2018; Knight, Wykes, & Hayward, 2006; Morrison et al., 2016; Wood, Byrne, Enache, & Morrison, 2018). These cognitive based interventions ranged from a brief formulation session (Wood, Byrne, Enache, & Morrison, 2018), to a more intensive 12-sessions utilising strategies to target appraisals and negative beliefs about self (Morrison et al., 2016). Three other studies (Ho et al., 2018; Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002; Russinova et al., 2014) delivered some form of psycho-education with a focus on providing information and opportunities to discuss the meaning and impact of stigmatising stereotypes alongside strategies to cope proactively. One study (Lysaker, Yanos, Outcalt, & Roe, 2010) followed a cohort of participants who were provided work placements of up to 20 hours per week over the course of five months.

1.5.4 Overview of the outcome measures used

Table 1 shows that studies commonly employed self report measures to investigate both internalised stigma and distress (n = 23). However, there is little agreement regarding the outcome measures used to reliably assess either internalised stigma or distress in the target population. Measures have therefore been outlined in Table 3 alongside key study findings.

Table 3.1.1 Relationship between internalised stigma and depressive symptoms - intervention studies

Cohort	IS measure	Depression measure	Association	Clinical relevance
Link et al. (2002)	PDD	CES-D	r = 0.41, p <0.001 B = 0.606, n.s., d = 1.53	IS associated with depression and explained 41.4% of the variance within a multiple regression. Impact of stigma intervention upon depression at follow-up not in the expected direction.
Knight et al. (2006)	PDD	BDI-II	Estimated change -6.46 p = .008, d = 0.70	Clinically significant reduction in depressive symptoms across the IS treatment period. Trend in symptom reduction continued at follow-up but change estimate not significant.
Russinova et al. (2014)	ISMI	CES-D	α = 0.92, p = .90, d = 0.03	No difference in depressive symptoms between IS intervention and control group post-, or follow-up.
Morrison et al. (2016)	ISMI, SIMS	BDI-PC	F = 4.39, p = 0.048, d = 0.59	Significant effect in favour of IS intervention for reducing depressive symptoms compared to control group. However this effect did not remain at follow-up.
de Jong et al. (2018)	ISMI	QIDS-SR	B = -0.07, n.s., d = -0.08	No significant effects of intervention in reducing depressive symptoms compared to control group.
Ho et al. (2018)	SSS-S	CDSS	B = 0.04, p = 0.021, d = 0.40	IS associated with depressive symptoms
Wood et al. (2018)	ISMI	BDI-PC	F = 0.682, p = 0.416, d = *-0.27* F = 1.411, p = 0.246, d = -0.33	No difference in depressive symptoms between IS intervention and control group post- therapy. No difference in depressive symptoms between groups at follow-up.

α Alpha, β Standardised Beta, *B* Un-standardised Beta, BDI - Beck Depression Inventory (Beck et al., 1961), BDI-PC - Beck Depression Inventory for Primary Care (Winter et al., 1999), CDSS - Calgary Depression Scale for Schizophrenia (Addington et al., 1993), CES-D - Centre of Epidemiological Studies Depression (Radloff, 1977), *d* Cohen's d effect size measure, IS Internalised Stigma, ISMI - Internalized Stigma of Mental Illness Scale (Ritsher et al., 2003), n.s. Non significant, PDD - Perceived Devaluation Discrimination Scale (Link, 1985; Link et al., 1991; Link et al., 2002), QIDS-SR - Quick Inventory of Depressive Symptomatology-Self Report (Rush et al., 2003), *r* Correlation coefficient, Rho Spearman's Rho, SIMS - Semi-structured Interview Measure of Stigma (Wood & Morrison, 2016), SSS-S - Self Stigma Scale Short Form (Mak & Cheung, 2010), SSMI - Self-Stigma of Mental Illness Scale (Corrigan et al., 2007).

Table 3.1.2 Relationship between internalised stigma and depression - observational studies

Cohort	IS measure	Depression measure	Association	Clinical relevance
Ritsher & Phelan (2004)	ISMI, PDD	CES-D	β = 0.24, *p* <0.05 β = -0.12, n.s.	IS predictive of depressive symptoms at follow-up when controlling for level at baseline. If stigmatising experiences occur without internalising then no significant effect.
Vauth et al. (2007)	PDD	CES-D/ADS	*r* = 0.19, *p* <0.01	Significant association between perceived stigma and depressive symptoms.
Kleim et al. (2008)	PDD	CES-D/ADS	*r* = -.03, n.s.	No significant association between perceived stigma and depression.
Norman et al. (2011)	SSMI	CDSS POMS-D	*r* = 0.25, *p* <.05 *r* = 0.53, *p* <.001	Significant association between IS and depressive symptoms as measured by both CDSS and POMS-D.
Sibitz et al. (2011)	ISMI PDD	CES-D/ADS	*r* = 0.28, *p* <0.01 *r* = 0.20, *p* <0.01	Significant association between depressive symptoms and IS as measured by both the ISMI and PDD.
Ben-Zeev et al. (2012)	SSMI	BDI, PANAS	*r* = 0.55, N/R	Significance of association between IS and depression not recorded.
Cavelti et al. (2014)	SSMI	CDSS, BDI-II	β = 0.27, *p* = 0.05	Increased IS between baseline and follow-up predicted depressive symptoms at 12 months.
Schrank et al. (2014)	ISMI	CES-D/ADS	*r* = 0.50, *p* = 0.01	Significant association between IS and depressive symptoms.
Lien et al. (2015)	ISMI	BDI-II	*r* = 0.36, *p* <0.01	Significant association between IS and depressive symptoms.
Valiente et al. (2015)	ISMI	BDI-II	β = -0.33, *p* <0.05	IS moderates the association between insight and depression explaining 7% of the variance in depressive symptoms.
Yoo et al. (2015)	ISMI	BDI	*r* = 0.521, *p* = 0.001	Significant association between IS and depressive symptoms.
Boyd et al. (2016)	ISMI	Symptom Checklist	β = 0.19, *p* <0.001 β = 0.18, *p* <0.001	IS was associated with increased depressive symptoms at 3-months when controlling for depression at baseline. This association continued at 6- month follow-up.
Collett et al. (2016)	SSMI	BDI	*r* = 0.46, *p* = 0.002	Significant association between IS and depressive symptoms.

Espinosa et al. (2016)	ISMI	BDI-II	r = 0.33, p <0.05	Significant association between IS and depressive symptoms.
Murri et al. (2016)	ISMI, PDD	CDSS	β = -0.5, N/R	The association between insight and depression was partially mediated by IS.
Lagger et al. (2018)	ISMI	CES-D/ADS	Rho = 0.38, p = 0.02	IS and depressive symptoms were related in their change over time.
Lien et al. (2018)	ISMI	BDI-II	r = 0.55, p <0.01	Significant association between IS and depressive symptoms.
Pellet et al. (2019)	SS	CDSS	r = 0.41, p = 0.001	IS predictive of depressive symptoms at follow-up, however this relationship was not significant after controlling for depressive symptoms at baseline.

β Standardised Beta, BDI - Beck Depression Inventory (Beck et al., 1961), CDSS - Calgary Depression Scale for Schizophrenia (Addington et al., 1993), CES-D - Centre of Epidemiological Studies Depression (Radloff, 1977), CES-D/ADS - German adapted shortened version of the CES-D (Hautzinger & Bailer, 1993), IS Internalised Stigma, ISMI - Internalized Stigma of Mental Illness Scale (Ritsher et al., 2003), N/R Not reported, n.s. Non significant, PANAS - Positive And Negative Affect Schedule (Watson et al., 1988), POMS - Profile Of Mood States (Curran et al., 1995), *r* Correlation coefficient, Rho Spearman's Rho, SCL-90-R - Symptom Checklist (Derogatis et al., 1973), SS - Stigma Scale (King et al., 2007), SSMI - Self-Stigma of Mental Illness Scale (Corrigan et al., 2007).

Table 3.2.1 Relationship between internalised stigma and anxiety symptoms - intervention studies

Cohort	**IS measure**	**Anxiety measure**	**Association**	**Clinical relevance**
Lysaker et al. (2010)	ISMI	MAQ	r = 0.37, p <.005 N/R, n.s.	Significant association between IS and anxiety symptoms. Social anxiety was not correlated with intervention participation.
Morrison et al. (2016)	ISMI, SSMI	SIAS	F = 3.19, p = 0.088, d = 0.68	No difference in effect of IS intervention for reducing social anxiety symptoms compared to control group.

d Cohen's d effect size measure, IS Internalised Stigma, ISMI - Internalized Stigma of Mental Illness Scale (Ritsher et al., 2003), MAQ - Multidimensional Anxiety Questionnaire (Reynolds, 1999), N/R Not reported, n.s. Non significant, *r* Correlation coefficient, SIAS - Social Interaction Anxiety Scale (Mattick & Clarke, 1998), SSMI - Self-Stigma of Mental Illness Scale (Corrigan et al., 2007).

Table 3.2.2 Relationship between internalised stigma and anxiety - observational studies

Cohort	IS measure	Anxiety measure	Association	Clinical relevance
Birchwood et al. (2006)	PBIQ	SIAS, FNE	O.R. 1.4, $p = 0.038$	Shame about psychosis was a predictor of social anxiety.
Norman et al. (2011)	SSMI	HARS POMS-A	$r = .28$, $p < .01$ $r = .31$, $p < .01$	Significant association between IS and anxiety symptoms as measured by both the HARS and POMS-A.
Ben-Zeev et al. (2012)	SSMI	BAI, PANAS	$r = .55$, N/R	Significance of association between IS and anxiety not recorded
Michael & Birchwood (2013)	PBIQ	SIAS, SPS	$F_{1,79} = 8$, $p < 0.05$	Shame about psychosis was significantly higher in the social anxiety group than control.
Valiente et al. (2015)	ISMI	BAI	$\beta = -1.59$, $p = 0.12$	IS did not moderate association between insight and anxiety symptoms.
Espinosa et al. (2016)	ISMI	BAI	$r = 0.97$, n.s.	No significant association between IS and anxiety was observed
Vrbova et al. (2017)	ISMI	BAI, LSAS	$t = 4.251$, $p = 0.0001$	IS levels were greater in the social anxiety group when compared to controls.

β Standardised Beta, BAI - Beck Anxiety Inventory (Beck et al., 1988), FNE - Fear of Negative Evaluation Scale (Watson & Friend, 1969), HARS - Hamilton Anxiety Rating Scale (Riskind et al., 1987), IS Internalised Stigma, ISMI - Internalized Stigma of Mental Illness Scale (Ritsher et al., 2003), LSAS - Liebowitz Social Anxiety Scale (Liebowitz, 1987), N/R Not reported, N.S. Non significant, O.R. Odds ratio, PANAS - Positive And Negative Affect Schedule (Watson et al., 1988), PBIQ - Personal Beliefs about Illness Questionnare (Birchwood et al., 1993), POMS - Profile Of Mood States (Curran et al., 1995), *r* Correlation coefficient, SIAS - Social Interaction Anxiety Scale (Mattick & Clarke, 1998), SPS - Social Phobia Scale (Mattick & Clarke, 1998), SSMI - Self-Stigma of Mental Illness Scale (Corrigan et al., 2007).

Table 3.3.1 Relationship between internalised stigma and shame symptoms - intervention studies

Cohort	IS measure	Shame measure	Association	Clinical relevance
Link et al. (2002)	PDD	SRF	r = 0.48 p <0.001 B = -0.072, n.s., d = -0.76	IS is associated with feeling ashamed and explained 38.9% of variance within a multiple regression. Impact of stigma intervention at follow-up was in the expected direction.
Morrison et al. (2016)	ISMI, SIMS	ISS	F = 4.84, p = 0.039, d = 0.56	Significant effect in favour of IS intervention for reducing shame symptoms compared to control group. However this effect did not remain at follow-up.

B Un-standardised Beta, *d* Cohen's d effect size measure, IS Internalised Stigma, ISMI - Internalized Stigma of Mental Illness Scale (Ritsher et al., 2003), ISS - Internalised Shame Scale (Cook, 1987), N/R Not reported, n.s. Non significant, PDD - Perceived Devaluation Discrimination Scale (Link, 1985; Link et al., 1991; Link et al., 2002), *r* Correlation coefficient, SIMS - Semi-structured Interview Measure of Stigma (Wood & Morrison, 2016), SRF - Stigma Related Feelings (Link et al., 2002).

Table 3.3.2 Relationship between internalised stigma and shame - observational studies

Cohort	IS measure	Shame measure	Association	Clinical relevance
Birchwood et al. (2006)	PBIQ	OSS, ISS	F = 9.7 p <0.001, d = 1.2	Participants in the social anxiety group appraised their psychosis as shameful, reporting significantly greater shame levels than the non-social anxiety group.
Michail & Birchwood (2013)	PBIQ	OSS, ISS	N/R, p = 0.41	There was no significant difference in shame symptoms between the psychosis and control group

d Cohen's d effect size measure, IS Internalised Stigma, ISS - Internalised Shame Scale (Cook, 1987), N/R Not reported, OAS - Other as Shamer Scale (Goss et al., 1994), PBIQ - Personal Beliefs about Illness Questionnare (Birchwood et al., 1993), *r* Correlation coefficient.

Table 3.4.1 Relationship between internalised stigma and negative affect (hostile, afraid, distressed) - observational studies

Cohort	IS measure	Affect measure	Association	Clinical relevance
Norman et al. (2011)	SSMI	POMS-A/H	r = 0.28, p <.01	Significant association between IS and negative affect as measured by the POMS-Anger/Hostility subscale.
Ben-Zeev et al. (2012)	SSMI	PANAS	r = .55, N/R	Significance of association between IS and negative affect not recorded.
Morgades-Bamba et al. (2019)	ISMI	PANAS	r = .59, p <.001 β = 0.20, p = 0.002	Significant association between IS and negative affect. Direct effect of IS on negative affect partially mediated by self-esteem.

β Standardised Beta, *d* Cohen's d effect size measure, IS Internalised Stigma, ISMI - Internalized Stigma of Mental Illness Scale (Ritsher et al., 2003), N/R Not reported, PANAS - Positive And Negative Affect Schedule (Watson et al., 1988), POMS - Profile Of Mood States (Curran et al., 1995), *r* Correlation coefficient, SSMI - Self-Stigma of Mental Illness Scale (Corrigan et al., 2007).

For the internalised stigma measures, a shift whereby some consensus around the use of the Internalised Stigma of Mental Illness (ISMI) scale (Ritsher, Otilingham, & Grajales, 2003) appears to occur from 2010-2011 onwards. This may reflect the work of Brohan, Slade, Clement, and Thornicroft (2010) who, through their systematic review of outcome measures, distinguished between perceived stigma and internalised stigma. Research now suggests that the Perceived Discrimination and Devaluation (PDD) scale (Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002) may measure both these conceptually different aspects of stigma (Wood, Byrne, Varese, & Morrison, 2016). The questionable reliability and validity of the PDD as a measure of internalised stigma therefore negatively affects the overall conclusions which might be drawn from a dataset including this measure.

Birchwood and his colleagues (Birchwood et al., 2007; Birchwood, Jackson, Brunet, Holden, & Barton, 2012; Michail & Birchwood, 2013) appear to have approached this concept differently, through their development of the Personal Beliefs about Illness Questionnaire. The PBIQ contains a set of subscales designed to capture key sets of negative beliefs an individual might hold about the cause, meaning, and consequences of psychosis (Birchwood, Jackson, Brunet, Holden, & Barton, 2012). As such, it might be considered well placed to investigate Brohan, Slade, Clement, and Thornicroft's (2010) conceptualisation of internalised stigma as an individual's internalisation of cognitions and emotions in response to public stigma. However the area of internalised stigma is relatively new, and therefore continues to develop more sophisticated measures for capturing these internalised stigma cognitions.

Again there was little agreement regarding the outcome measure used for depressive symptoms, and three studies chose to use more than one approach to quantify this outcome. As described within Cavelti, Rüsch, and Vauth (2014), the choice to employ observer rated measures alongside

participants' self report was related to the potential confounding effects of participant insight into illness when completing self report measures.

Other distress outcomes measured included anxiety (*n* = 6), social anxiety (*n* = 4), shame (*n* = 4), and negative affect (*n* = 3). One study (Lysaker, Yanos, Outcalt, & Roe, 2010) chose to use the Multidimensional Anxiety Questionnaire (MAQ) to specifically investigate social anxiety. The number of studies focusing on these other forms of distress are noticeably fewer than the twenty six targeting depression, and continues to be a developing area for research. Significant differences ($t = 3.175$, $p<0.005$) were found in more general anxiety levels between groups comparing those with and without social anxiety in the one study (Vrbova, Prasko, Ociskova, & Holubova, 2017) which contained a measure specifically for social anxiety alongside a more general measure of anxiety.

1.6 General discussion

The associations between internalised stigma and psychological distress as measured by the studies within this review are summarised in Table 3. Associations between IS and each of the key emotional responses highlighted within Wood, Byrne, and Morrison's (2017) model are considered in the following sections.

Depression

The principle outcome of distress used was depression, employed by 26 of the 30 included studies. Overall, findings suggest that there is a significant positive association between internalised stigma and level of depressive symptoms (Collett, Pugh, Waite, & Freeman, 2016; Espinosa, Valiente, Rigabert, & Song, 2016; Lien et al., 2015; Lien et al., 2018; Norman, Windell, Lynch, & Manchanda, 2011; Schrank, Amering, Grant Hay, Weber, & Sibitz, 2014; Sibitz et al., 2011; Vauth, Kleim, Wirtz, & Corrigan, 2007; Yoo et al., 2015). This overall pattern might be considered in line with predictions made in all three of the IS models (i.e. Link & Phelan, 2001; Birchwood et al., 2007; Wood et al., 2017) previously discussed.

However in contrast to this pattern, Kleim et al. (2008) did not find a significant or positive association between internalised stigma and depressive symptoms. Despite Kleim et al. (2008) recruiting a sample size of 127 participants, all with a diagnosis of schizophrenia, which is appropriate to observe the effect without heightened risk of Type II error, it is necessary to consider other contributing factors. Other factors which may contribute to the observed contrasting pattern in association between IS and depressive symptoms include the possible impact of confounding variables left uncontrolled. The importance of recognising potential confounding variables is acknowledged through the QAT (National Institute for Health, 2017) and is a factor that limits Kleim et al.'s (2008) study in comparison to other observational studies.

One controversial confounding variable is the potential overlap between depression and negative psychotic symptoms. Evidence from studies which do control for this potential overlap provides further support for the dominant pattern (Cavelti, Rusch, & Vauth, 2014; Ho et al., 2018; Murri et al., 2016). This might also highlight the necessity of an increasing shift in emphasis by Birchwood et al. (2007) and later Wood et al. (2017) towards a model specific to the experiences of people with psychosis.

When entered into regression analyses, internalised stigma was found to be an independent predictor of depression (Boyd, Hayward, Bassett, & Hoff, 2016; Cavelti, Rusch, & Vauth, 2014; Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002; Ritsher & Phelan, 2004; Valiente, Provencio, Espinosa, Duque, & Everts, 2015). Furthermore, evidence from Lagger, Amering, Sibitz, and Schrank (2018) suggests that internalised stigma and depression relate in their changing levels over time. Interestingly, one study (Ritsher & Phelan, 2004) supported evidence for this pattern but asserted that if stigmatising experiences occurred without the individual internalising them, then no significant effect was observed.

Whilst no studies report on depression as a primary outcome, experimental studies which reported upon depression as a secondary outcome provide little support for the use of stigma focused interventions in reducing psychological distress in the form of depressive symptoms. One early study (Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002) reported a non significant intervention effect upon depression that was not in the expected direction for their experimental group. This outcome might be better understood in the context of a psycho-education based intervention being employed which focused on teaching participants about recognising the possibility of internalising stigma and choosing ways to cope with stigmatising encounters rather than any cognitive restructuring to support change in existing cognitions despite acknowledging high levels of IS in the sample group (Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002). Study findings are further confounded by the use of an internalised stigma measure more recently found to be unreliable.

Two studies (Knight, Wykes, & Hayward, 2006; Morrison et al., 2016) reported that their intervention designed to focus upon internalised stigma had resulted in a significant (moderate effect size) reduction in depression symptoms post-treatment, but that this effect had not been observed at follow up. Two further studies (de Jong et al., 2018; Wood, Byrne, Enache, & Morrison, 2018) reported that their internalised stigma based intervention did not exert any significant effect upon depressive symptoms reported by participants when they were compared to the control group.

Findings from the reviewed studies are therefore inconclusive as to whether treatment interventions designed to reduce internalised stigma can produce a lasting reduction in participants' depressive symptoms. Whilst it is possible to find evidence for interventions that reduce an individual's sense of internalised stigma, the challenge remains for researchers and clinicians to develop an intervention that reduces the emotional distress people experience as a consequence of stigma.

Anxiety

Nine studies utilised measures of internalised stigma and anxiety. Whilst two studies (Lysaker, Yanos, Outcalt, & Roe, 2010; Norman, Windell, Lynch, & Manchanda, 2011) reported a significant positive association between internalised stigma and anxiety, Espinosa, Valiente, Rigabert, and Song's (2016) non significant findings do not support this as a more general pattern of relationship. Two studies notable for their specific focus upon social anxiety provide tentative evidence for a relationship between the experience of internalised stigma and social anxiety, as opposed to more general anxiety symptoms (Birchwood et al., 2007; Michail & Birchwood, 2013). This appears consistent with the work of Link and Phelan's (2001) and Birchwood et al. (2007), as their models of IS both predict that emotional distress results from an individual developing appraisals that others will reject them.

In Birchwood et al.'s (2007) study, participants with psychosis who believed their diagnosis to be shameful were found to be a predictor of social anxiety symptoms. Michail and Birchwood's (2013) later study provides further support for a relationship between internalised stigma and social anxiety, as they found that participants with psychosis expressed higher levels of shame about their diagnosis if they were also socially anxious. However, whilst a relationship appears to exist between internalised stigma and social anxiety, the directionality of possible effect the variables exert on each other within this relationship remains unclear.

Shame

Four studies utilised measures of internalised stigma and shame, however only one of these (Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002) investigated the association to report a significant positive relationship between them. The two studies (Link, Struening, Neese-Todd, Asmussen, & Phelan, 2002; Morrison et al., 2016) with interventions designed with a focus on internalised stigma reported post treatment reductions in shame. Despite findings of an effect on shame levels in the expected direction, it was not

significant at follow up. These inconsistent effects may be in part explained by the other studies investigating shame.

While participants with psychosis did report significant levels of shame, and appraised their diagnosis as shameful, this was in a group who also reported high levels of social anxiety (Birchwood et al., 2007). When controlling for social anxiety, Michail and Birchwood (2013) did not find a significant difference in shame levels for participants with psychosis with similar appraisals of their diagnosis. These outcomes are therefore inconclusive as to the nature of the relationship between internalised stigma and shame. Wood et al.'s (2017) more nuanced model with bi-directional predictions between key aspects of IS might therefore be able to provide greater clarity when attempting to understand emotional distress in people who experience psychosis.

Negative Affect

Three studies utilised measures to explore dimensions of negative affect such as hostility and generalised distress (Ben-Zeev, Frounfelker, Morris, & Corrigan, 2012; Morgades-Bamba, Fuster-Ruizdedapodaca, & Molero, 2019; Norman, Windell, Lynch, & Manchanda, 2011). Whilst a consistent relationship appears to exist between IS and negative affect, findings from longitudinal research studying other aspects of distress suggest that baseline distress (e.g. depression) is the main predictor in evolution of distress at later timepoints (Pellet et al., 2019).

The implications of these findings is that at present insufficient evidence exists for a key element of Wood, Byrne, and Morrison's (2017) cognitive model of internalised stigma in psychosis. Although stigmatising appraisals and beliefs are hypothesised to hold a bi-directional relationship with emotional reactions, evidence appears inconclusive in key expressions of emotion such as depression and anxiety.

It is possible that another underlying mechanism is involved within the relationship between self and other knowledge and mood. Results from studies such as Valiente et al. (2015) and Murri et al. (2016) indicate that an individual's insight may also affect this relationship. This may explain why studies have found a correlational association, but interventions have not yet observed changes in secondary outcomes such as depression in the expected direction.

1.6.1 Limitations and future directions

This review excluded studies which were not published in English language. Findings therefore do not include the four studies identified within systematic searching or reflect the potential relationships between IS and distress in those geographical areas. Included studies focused upon specific measures of distress in the form of depression, anxiety, and shame whilst excluding multi-dimensional measures of distress. Although excluding multi-dimensional measures allowed for the exploration of specific relationships, broader expressions of emotional distress out with these categories remain unaccounted for.

The definition of 'distress' across different studies affects the interpretation of synthesised results. A number of pathways to psychological distress for people who experience psychosis have been indentified (Birchwood, 2003) and as such, it is increasingly important to recognise this within research methodology. However, with few studies investigating the association between internalised stigma and distress, it was necessary to include studies which did not account for the separate pathways of; distress as intrinsic to the experience of psychosis, distress as a response to intrusions, and distress as a response to stigmatising diagnosis. It is therefore prudent to be mindful that some inconsistency continues to exist when assessing the concept of distress.

This review also did not include studies which reported upon sub-clinical samples. As such it was not possible to report or compare data for individuals in different stages of psychosis (i.e. high risk, prodrome, first episode, multi episode). It has been suggested (Gerlinger et al., 2013) that individuals may have different experiences of stigma at each stage and this may lead to differences in internalised stigma cognitions. Further investigation into the relationship between internalised stigma and distress for individuals at each stage is recommended.

The limitations of this review, and limitations of included studies increasing potential risk of bias identified in this review, highlight a number of important future directions for research. Although evidence from this review is suggestive of a relationship between internalised stigma and distress, whether these negative beliefs about the self in relation to others around them leads to distress remains inconclusive. To support a developing evidence base, researchers may need to continue with careful consideration of their study measures so as to reliably capture the potential range of participants' experiences of distress.

Although a greater number of studies are using comprehensive and validated measures of distress rather than just a one question measure, reliable and valid measures to capture a range of expressions of psychological distress continue to be under used. Recommendations of this current review echo that of Mawson, Cohen, and Berry (2010) and call for interventions to directly address distress as a key aim and refinement to protocols. Although this has been achieved in part as more recent studies have included secondary outcomes, it remains an under investigated or under reported area. Future experimental studies may wish to include specific measures of distress, for example depression or anxiety, as secondary outcomes when targeting cognitive appraisals.

1.6.2 Conclusion

This systematic review builds on other reviews examining the importance of self and social knowledge in the form of internalised stigma for people who experience psychosis. A pattern of association between internalised stigma and distress in the form of depressive symptoms was found across the majority of reviewed studies. However, evidence remains inconclusive regarding any association between other possible forms of psychological distress. Furthermore, experimental designs that focused on internalised stigma did not consistently lead to clinically significant reductions in depressive symptoms post treatment. Based on evidence so far, further high quality research is recommended to evaluate the efficacy of interventions which focus on cognitive appraisals of the self in relation to others as a potential method of reducing distress in psychosis.

1.7 References

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1.8 Author Disclosure Statements

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Contributors

HP and HG designed the study and wrote the protocol. HP conducted the literature search, before screening all articles by title, abstract, and full-text. HP wrote the first draft, and all authors have contributed to and have approved the final manuscript.

Disclosure of interest

The authors report no conflict of interest.

Chapter 2: Empirical Study

2.1 Title Page²

Title: The mediating role of self and social knowledge between attachment and distress in psychosis.

Short title: Self and social knowledge in psychosis

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2.2 Abstract:

Objectives. Effective social information processing can help manage the potential threat of stigma for those who experience psychosis. This study aims to explore the relationship between attachment, reflective functioning, cognitive appraisals, and emotional distress in people who experience psychosis.

Design. This study employed a cross-sectional design.

Methods. Twenty-seven service users completed a questionnaire pack and interview examining attachment, emotional distress, reflective functioning, cognitive appraisals, and symptomatology. Correlation and multiple regression analysis were conducted on the data, with mediation modelling used to explore cognitive appraisals as mediatory variables.

Results. Attachment anxiety was significantly related to cognitive appraisals such as personal beliefs about illness, and distress (depression, generalised anxiety, social anxiety) but not to reflective functioning. Attachment anxiety and cognitive appraisals were found to predict distress including when controlling for symptoms of psychosis. Cognitive appraisals were found to mediate the relationship between attachment anxiety and emotional distress.

Conclusions. People with psychosis whose attachment model is of personal unworthiness, leading to anxieties about rejection, are likely to experience emotional distress. Whilst reflective functioning was not found to influence this association, holding negative beliefs about the self in relation to others was found to mediate this relationship. Negative appraisals about the self and illness may therefore be targeted as potential maintenance factors when treating emotional distress in people who experience psychosis.

Keywords:

schizophrenia; psychosis; cognitive model; appraisals; attachment; distress

Practitioner Points:

- Attachment anxiety is significantly related to emotional distress (depression, generalised anxiety, social anxiety).
- Negative personal beliefs about illness mediated the relationship between attachment anxiety and emotional distress in psychosis. Individuals with heightened attachment anxiety were more likely to experience greater negativity in appraisals relating to shame and control.
- Clinical approaches should consider the potential influence of cognitive appraisals about the self in relation to others upon emotional distress when formulating service user experiences of psychosis.

Data availability statement:

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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This study was completed as part of a Doctorate in Clinical Psychology, undertaken with the University of Edinburgh and NHS Forth Valley.

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[1]Produced according to author information and submission guidelines for Psychology and Psychotherapy: Theory, Research and Practice (see Appendix B). Tables and figures however, are inserted alongside corresponding text as per recommendations for thesis submission.

[2]Numbering of titles is included throughout for continuity of thesis portfolio, but would not be included for journal submission.

The mediating role of self and social knowledge between attachment and distress in psychosis.

2.3 Introduction

People with psychosis commonly experience mood disorders such as anxiety and depression (Buckley, Miller, Lehrer, & Castle, 2009). High prevalence rates of depression in schizophrenia spectrum disorders are reported, with estimates around 40% (Upthegrove, Marwaha, & Birchwood, 2017). However rates can vary from 20-60% with factors such as stage of illness (Upthegrove, Marwaha, & Birchwood, 2017) and cognitive insight (Palmer, Gilleen, & David, 2015) influencing figures. Upthegrove (2009) asserted that depression in schizophrenia had been a neglected area of the field. This assertion was made in the context of evidence that depression is related to poor recovery outcomes and increased risk of relapse (an der Heiden, Konnecke, Maurer, Ropeter, & Hafner, 2005). In response, research initially focused upon depression as a measure of distress. However evidence also suggests that different types of anxiety also play a role in the lives of people who experience psychosis (Huppert & Smith, 2005).

Hall (2017) argues that the heightened anxiety levels can bias both perception and cognition, and is therefore important in understanding people's experience of psychosis. Birchwood *et al.* (2006) suggest that the social anxiety experienced by a number of people with psychosis is associated with shame appraisals of the diagnosis. Shame appraisals hamper emotional recovery from psychosis due to the strong association between shame and depression in this population (Keen, George, Scragg, & Peters, 2017). This study will build upon the evidence base which has most frequently taken depression as a measure of emotional distress by including measures of generalised anxiety, and social anxiety.

Social Mentality Theory (SMT) is considered to be a useful framework for understanding a person's adaptation to the experience of psychosis

(MacBeth, Schwannauer, & Gumley, 2008). Similarly, Birchwood *et al.* (2006) comment that receiving a diagnosis of psychosis may be experienced as a challenge to an individual's identity due to issues of stigma and social desirability. Experiencing such a challenge to current identity might therefore lead an individual to adapt their appraisals of the self, including in relation to others. This is consistent with the views of Morrison (2001) who emphasised that beliefs about cultural acceptability can shape the appraisals people make about their anomalous experiences. A diagnosis of psychosis may reinforce an individual's beliefs that their experiences are not culturally acceptable thus prompting reappraisal of social desirability.

Birchwood (2003) highlighted this process of adaptation as a possible pathway to emotional distress. How individuals appraise the personal threat of their psychosis diagnosis was proposed to differ by perceptions of shame due to stigma and changes in social rank (Birchwood, 2003). This view is supported by Iqbal, Birchwood, Chadwick, and Trower (2000) who found that participants holding cognitive appraisals that their diagnosis of psychosis had enforced a lower social status experienced distress in the form of depression. Research suggests that many people with psychosis associate their illness status with high levels of shame, blame, and fear of discrimination (Corrigan & Watson, 2002; Brohan, Slade, Clement, & Thornicroft, 2010).

Attachment is described by Mikulincer, Shaver, and Pereg (2003) as one of the most important conceptual frameworks for understanding how an individual regulates their emotions. The attachment system functions to monitor and appraise potentially threatening events before activating mental representations of strategies to facilitate security with the aim of coping with any distress that arises from the threat (Mikulincer, Shaver, & Pereg, 2003). These mental representations are hypothesised to become working models which guide an individual's attention, interpretations, and predictions about themselves and others within the social environment (Waters & Waters, 2006).

Bartholomew and Horowitz (1991) suggest both positive and negative models of the self and the other working models can be formed. The resultant four attachment styles were then proposed to split across two dimensions; attachment anxiety (associated with model of the self) and attachment avoidance (associated with model of others). Whilst research has traditionally assessed attachment style categorically (eg. secure, insecure-anxious, insecure-avoidant), evidence suggests that adult attachment can fluctuate in the dimensions (Fraley, Vicary, Brumbaugh, & Roisman, 2011). To account for these fluctuations, researchers have increasingly assessed attachment across the dimensions of anxiety and avoidance. This approach has been recommended due to its less restrictive nature (Wickham, Sitko, & Bentall, 2014).

Research by Berry, Barrowclough, and Wearden (2008) using the Psychosis Attachment Measure (PAM) with participants diagnosed with schizophrenia spectrum disorders found that attachment ratings were relatively stable over time. Despite this relative stability, they (Berry, Barrowclough, & Wearden, 2008) reported that changes in the dimension of attachment anxiety were positively correlated with changes in symptoms. This finding is supported by a more recent systematic review which reported insecure anxious attachment to be associated with psychotic symptomatology (Korver-Nieberg, Berry, Meijer, & de Haan, 2014). However, it is important to note that this association is not unanimous within research, as Pickering, Simpson, and Bentall (2008) reported the strength of association reduced after controlling for confounders.

A different avenue of research has investigated the potential attachment style might hold for predicting distress in people who experience psychosis. This is due to the proposed relationship between internal working models and social rank through the internalisation of secure attachment where others are regarded safe/helpful/supportive, as this means safeness is activated socially

(MacBeth, Schwannauer, & Gumley, 2008). Conversely, those with insecure attachment may find social rank to be a source of threat, and due to their increased focus upon threat, an attentional bias towards issues of social rank may be observed (Laithwaite *et al*., 2009). If an individual perceives their diagnosis of psychosis as a threat, the attachment system will be activated and their individual working models might be expected to guide that person's attention, interpretations, and predictions about the themselves and others.

Mikulincer and Shaver (2012) state there is evidence for an association between attachment style and emotional distress. This is further supported by a systematic review which reported associations between attachment insecurity and depression in people who experience psychosis (Gumley, Taylor, Schwannauer, & MacBeth, 2014). It was proposed by Mikulincer and Shaver (2012) that the dimension of attachment anxiety is characterised by heightened emotional distress. Research utilising this dimensional approach reported attachment anxiety was significantly associated with anger ($r = 0.37$, $p< 0.001$) and depression ($r = 0.56$, $p< 0.001$) in a sample group of people with psychosis (Darrell-Berry, Bucci, Palmier-Claus, Drake, & Berry, 2017). This study seeks to extend current research exploring the relationship between attachment anxiety and emotional distress.

Research has also indicated a possible relationship between stigma and emotional distress. Wood and Irons (2017) report positive correlations between experienced stigma and both depression ($r = 0.446$, $p< 0.01$) and anxiety ($r = 0.474$, $p< 0.01$). Furthermore, the impact of these stigmatising experiences on depression was mediated by shame appraisals (Wood & Irons, 2017). High levels of stigma around psychosis continues to exist in society, with 87% of respondents to a recent report disclosing direct experience (Schizophrenia Commission, 2012). It is therefore important to investigate the ways in which people process social information about themselves and other people.

One cognitive process which might change an individual's illness appraisals around psychosis and therefore the impact of diagnosis itself is reflective functioning. Reflective functioning relates to the capacity of an individual to understand the mental states of themselves and others, including cognitions and affective state (MacBeth, Gumley, Schwannauer, & Fisher, 2011). Reflective functioning is argued to develop within the context of secure attachment relationships where the individual holds a positive working model of both themselves and others (Fonagy *et al*., 2016). However, if environments which offer relational security promote reflective functioning, environments which are perceived as interpersonally threatening might therefore lead to a reduction in reflective functioning.

Gilbert (2000) argues that emotional expressions of distress such as shame, anxiety and depression might be conceptualised as submissive strategies when individuals find themselves in position of unwanted low status/social rank positions. This is particularly pertinent for people with a diagnosis related to psychosis who not only experience stigma but are also reported to internalise these experiences (Wood & Irons, 2017). The emotional impact of diagnosis might therefore remain stable with additional insight until the unwanted social ranking position is cognitively reappraised.

This study aims to build upon current evidence examining the relationship between the patterns of how people relate to other people in order to have their needs met (attachment style) and forms of emotional distress such as anxiety and depression. It will also investigate the thoughts and feelings people use about themselves and others to make sense of social situations (reflective functioning and cognitive appraisals) as potential mediating variables within this relationship. It is hypothesized that: (1) attachment anxiety, greater difficulty in reflective functioning, and greater negativity in cognitive appraisals of the self in relation to others will be positively associated with higher levels of emotional distress; and (2) reflective

functioning and cognitive appraisals will mediate the relationship between attachment anxiety and emotional distress.

2.4 Method

2.4.1 Participants

Participants were recruited from secondary care services in Central Scotland, United Kingdom. Potential participants were identified and then approached by their care coordinator/keyworker from within the Integrated Community Mental Health Team and inpatient wards, including rehabilitation wards. Inclusion criteria were: (1) a diagnosis related to the symptoms of psychosis as determined by the treating clinician; (2) aged 16+; (3) willing to participate voluntarily and able to give written informed consent; (4) sufficient understanding of English to complete the measures. Participants were excluded if they were unable to give informed consent, were unable to communicate in English, or had a history of organic factors implicated in the aetiology of psychotic symptoms e.g. brain injury. If the potential participant consented, they were contacted by the researcher to ask whether they wished to participate.

Sample size was calculated according to guidance within Fritz and MacKinnon's (2007) article on planning to test mediated effects. Examination of previous literature suggested large effect sizes for the attachment-reflective functioning and attachment-cognitive appraisals. To achieve 0.8 power, Fritz and MacKinnon (2007) recommend a lower limit of 34 participants.

2.4.2 Measures

The self-report version of the Psychosis Attachment Measure (PAM; Berry, Wearden, Barrowclough, & Liversidge, 2006) was used as an independent variable. It has 16 items, with participants asked to rate each item using a 4-point scale ranging from ‘not at all’ to ‘very much’. The PAM is based on existing measures of attachment along the axes of anxiety and avoidance

proposed by Bartholomew and Horowitz (1991). For the purposes of this study, only the axis of attachment anxiety was used with higher scores on the measure illustrating higher levels of negativity in participants' working model of the self. The PAM was found to have an acceptable level of internal consistency in this study (Cronbach's α for both dimensions = 0.67).

Two potential mediator variables were used. The Reflective Functoning Questionnaire (RFQ; Fonagy *et al*., 2016) is an 8-item screening measure of reflective functioning. Each item of the measure provides a statement such as "I always know what I feel" to which participants are invited to respond using a 7-point scale from 'strongly disagree' to 'strongly agree'. The RFQ within this study held acceptable reliability and validity (Cronbach's α = 0.67). In line with previous studies (eg. Perkins, 2009; Ha, Ensink, Fonagy, & Cirino, 2013) a total score was calculated, with higher total scores illustrating greater difficulty in reflective functioning.

The Personal Beliefs about Illness Questionnaire – Revised (PBIQ-R; Birchwood, Jackson, Brunet, Holden, & Barton, 2012) is a 20-item self-report measure designed to reflect current constructs of social rank theory in relation to people experiencing psychosis. These five constructs are named as; shame, loss, entrapment, control over illness, and social marginalization/group fit. The PBIQ-R was found to be internally consistent (Cronbach α values for all five subscales between 0.62 and 0.65). In line with previous studies (eg. Braehler *et al*., 2012) a total score was calculated alongside subscale scores, with higher scores illustrating less favourable beliefs about the self and psychosis.

A composite dependent variable was comprised of three measures of emotional distress. This is in acknowledgement of anxiety and depression as the most commonly experienced expressions of emotional distress for people with psychosis (Buckley, Miller, Lehrer, & Castle, 2009). However research also suggests that future choice of anxiety measures should include a

measure of social anxiety alongside generalised anxiety as this facet of anxiety is more likely to be impacted upon by stigma (Wood & Irons, 2017).

The Generalized Anxiety Disorder Scale (GAD-7; Spitzer, Kroenke, Williams, & Lowe, 2006) is a 7-item self-report screening measure designed as a diagnostic and to assess symptom severity. Participants are invited to respond indicating how often they have been bothered by each of the seven itemised problems across four rating points from 'not at all' to 'nearly every day'. The Social Interaction Anxiety Scale (SIAS; Mattick & Clarke, 1998) is a self-report questionnaire designed to assess generalised fears of social interaction. Participants are invited to “indicate the degree to which you feel the statement is characteristic or true about you” over a scale of 19 items across five rating points from ‘not at all’ to ‘extremely’. The Calgary Depression Scale for Schizophrenia (CDSS; Addington, Addington, & Schissel, 1990) is a 9-item structured interview which is regularly used within research. A total score was calculated, with higher scores illustrating greater emotional distress. The distress composite variable was found to have acceptable internal consistency for this study (Cronbach's $\alpha = 0.77$).

A relatively low level of internal consistency is acknowledged. However, alpha coefficients for each of the measures were evaluated by taking into account this study's specific circumstances. Apart from the RFQ, each individual outcome measure was chosen for being well developed and validated with a psychosis sample group. Alpha coefficients might therefore be better understood in the context of a small sample size and wide variation in sample group as later highlighted within study demographics.

2.4.3 Procedure

This study received approval from an NHS Research Ethics Committee and was undertaken as part of the first author's doctoral thesis. A one-off meeting was scheduled with those who consented to participate in the study either in their own home or at their local mental health service. Written consent was

obtained from participants before the questionnaire pack and interview was administered by the first author. Participants were given the option of completing the questionnaire pack independently or with the support of the researcher. Interviews were audio-recorded for the purposes of ensuring coding accuracy.

2.4.4 Statistical analysis

Statistical analyses were conducted using SPSS version 23. All data were checked against the assumptions for parametric analysis, and variables were found to be normally distributed (except the BCSS Negative Self subscale). Pearson correlation coefficients were used to explore the relationships between all variables. Linearity was explored with 1 outlier identified and removed as it did not meet the threshold in both Cook's distance and Leverage values. Mediation models were calculated using the SPSS PROCESS macro using Preacher and Hayes' (2004) bootstrap method with 1000 replications. This bias corrected bootstrap method was selected in acknowledgement of the potential for small sample sizes to compromise the conclusions drawn from a study. A mediating effect was considered present if a statistically significant indirect effect of a mediator was found in the relationship between attachment anxiety and distress, or if the strength of that relationship reduced when the mediator was introduced.

2.5 Results

2.5.1 Demographics and clinical characteristics

A total of 27 participants were recruited and included in the analysis, 9 of whom were female and 18 were male with an average age of 44 years (*SD,* 13.48: range 21-66). See Table 1 for demographic characteristics of the sample. Four further service users were invited to participate by clinicians, of which three declined and one was excluded for not meeting diagnosis inclusion criteria. All participants had experienced psychotic symptoms, and the average age of onset for the sample was 25.52 (*SD*, 7.21: range 16-40).

Table 1. Demographics of the study sample

Variable	*N*	%
Gender		
Male	18	67
Female	9	33
Relationship status		
Single	20	74
In a relationship	5	19
Separated	2	7
Primary diagnosis		
Schizophrenia	11	41
Paranoid schizophrenia	8	30
Schizoaffective	3	11
Bipolar affective disorder	2	7
Psychosis	3	11
Service type		
Community mental health team	16	59
In-patient rehabilitation unit	8	30
In-patient acute ward	3	11

Descriptive data for outcome measures can be found in Table 2. The sample group reported clinically low PANSS symptomatology with Positive (mean=14.89, *SD*, 5.43: range 9-26), Negative (mean=13.78, *SD*, 5.07: range 9-29), and General Psychopathology (mean=32.30, *SD*, 9.15: range 19-55) symptom scores falling below the clinical cut off advised by Kay, Opler, and Lindenmayer (1988) for each subscale. The sample group reported moderate attachment anxiety (mean=1.46, *SD*, 0.65: range 0.25-2.75). However low reflective functioning was reported (mean=1.83, *SD*, 0.65: range 0.67-3.50) which is perhaps unexpected when viewed alongside the clinically low PANSS symptomatology and moderate levels of attachment anxiety reported.

Symptom scores fell just below the clinical cut off scores for generalised anxiety (mean=8.78, *SD*, 5.98: range 0-20) and social anxiety (mean=27.37, *SD*, 15.13: range 1-60), however above the clinical cut off for depression (mean=7.81, *SD*, 5.68: range 0-22). The PBIQ-R total scores reported (mean=49.26, *SD*, 10.11: range 24-68) are in line with scores reported for a

first episode psychosis sample group with clinical levels of depression (Birchwood, Jackson, Brunet, Holden, & Barton, 2012). The wide range of scores is of note and may reflect variations in the sample stage of illness.

Table 2. Descriptive data for all outcome measures

Measure	Mean	*SD*	Minimum	Maximum
PAM Anxiety	1.46	.65	0.25	2.75
PAM Avoidance	1.00	.44	0.25	1.75
PBIQ-R Total	49.26	10.11	24	68
Shame	9.81	2.63	4	15
Loss	9.81	2.45	4	15
Entrapment	10.37	2.53	5	15
Control	9.89	2.95	4	16
Social Marginalisation	9.37	2.45	5	15
PANSS	28.67	7.70	19	51
RFQ8	1.83	0.81	0.67	3.50
Distress Total	43.96	23.01	2	80
GAD	8.78	5.98	0	20
SIAS	27.37	15.13	1	60
CDSS	7.81	5.68	0	22

Note. SD = Standard Deviation; PAM = Psychosis Attachment Measure; PBIQ-R = Personal Beliefs about Illness Questionnaire-Revised; PANSS = Positive and Negative Syndrome Scale combined symptom scores; RFQ8 = Reflective Functioning Questionnaire; GAD = Generalised Anxiety Disorder Questionnaire; SIAS = Social Interaction Anxiety Scale; CDSS = Calgary Depression for Schizophrenia Scale.

2.5.2 Predictors of emotional distress hypothesis

Pearson correlation coefficients (see Table 3) illustrated that the key variables of attachment anxiety, PBIQ-R, and distress were significantly related to one another. Attachment anxiety was strongly positively correlated with the PBIQ-R total, and Distress variables. Attachment avoidance was also significantly associated with the composite variable of distress and with the PBIQ-R, holding particularly strong positive associations with the subscales of Shame and Control.

PBIQ-R subscales of Shame, Loss, and Control were also strongly positively correlated with distress. Reflective functioning was not significantly related to other mediator (PBIQ-R) or outcome (distress) variables and was therefore not included within mediation analysis.

Table 3. Pearson's correlation matrix, means, and standard deviations for all measures

Measure	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.	12.	13.	14.	15.
1. PAM Anxiety															
2. PAM Avoidance	.473*														
3. PBIQ-R Total	.510***	.535***													
4. Shame	.534***	.528***	.766***												
5. Loss	.368	.450*	.898***	.543***											
6. Entrapment	.039	.039	.644***	.230	.626***										
7. Control	.581***	.624***	.801***	.566***	.672***	.361									
8. Social Marginalisation	.422*	.396*	.776***	.625***	.665***	.447*	.447*								
9. PANSS	-.009	-.118	-.348	-.425*	-.226	-.225	-.301	-.160							
10. RFQ8	-.212	-.093	.165	.021	.171	.234	.134	.085	.072						
11. Distress Total	.538***	.401*	.711***	.645***	.666***	.650***	.418*	.407*	-.014	.144					
12. GAD	.567***	.426*	.584***	.584***	.580***	.232	.573***	.273	-.094	-.125	.845***				
13. SIAS	.419*	.303	.662***	.601***	.643***	.399*	604**	.304	-.061	.257	.943***	.703***			
14. CDSS	.465*	.369	.501**	.399*	.373	.203	.418*	.552***	.206	.030	.647***	.496**	.412*		
15. Age	.187	.122	.027	.043	-.086	.159	-.002	-.010	.068	-.080	.047	.077	-.083	.329	
16. Gender	.108	.023	.108	.233	-.044	.306	.054	-.142	-.406*	.055	.172	.187	.125	.164	.489***

*** Correlation is significant at the alpha corrected level (2-tailed),
** Correlation is significant at the 0.01 level (2-tailed), * Correlation is significant at the 0.05 level (2-tailed).

Note. PAM = Psychosis Attachment Measure; PBIQ-R = Personal Beliefs about Illness Questionnaire-Revised; BCSS NS = Brief Core Schema Scale Negative Self; RFQ8 = Reflective Functioning Questionnaire; GAD = Generalised Anxiety Disorder Questionnaire; SIAS = Social Interaction Anxiety Scale; CDSS = Calgary Depression for Schizophrenia Scale.

Age, gender, and PANSS symptom scores were examined as a potential confounding variable in relation to the main study variables. There were no significant correlations between age, gender, or PANSS symptom scores with attachment anxiety, reflective functioning, or distress. Furthermore, the combined PANSS positive and negative symptom scores were not correlated with any variables other than shame from the PBIQ-R. Due to the significant association identified, PANSS symptoms were controlled for within exploratory mediation analysis where PBIQ-Shame was entered as a potential mediator.

2.5.3 Mediation analysis

Results from mediation analysis showed attachment anxiety exerted a significant effect on emotional distress indirectly through personal beliefs about illness (see Figure 1). The 'a' path (attachment anxiety-personal beliefs about illness) and 'b' path (personal beliefs about illness-emotional distress) were both found to be significant (a = 8.40, p=0.0089; b = 1.27, p=0.0009). A bias-corrected bootstrap confidence interval for the indirect effect (path 'ab' = 24.47, p=0.0005) did not contain zero (2.10-25.30). The direct effect of attachment anxiety on emotional distress (c' path) remained significant (c' = 13.70, p=0.0226). This model (including predictor variables) explained 40.38% of the variance in emotional distress.

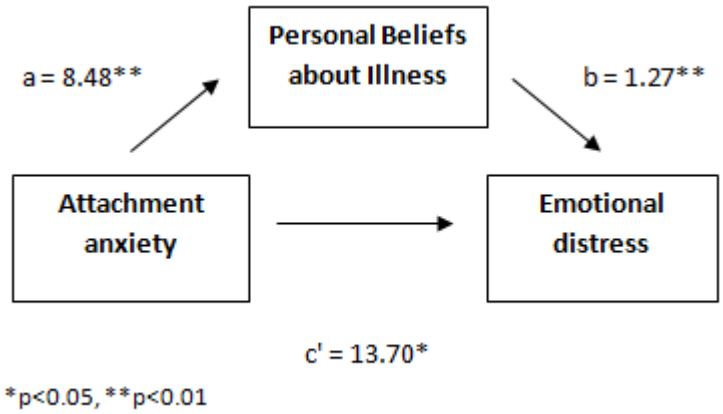

Figure 1. Mediation model of PBIQ-R, attachment anxiety and distress.

2.5.4 Exploratory analysis

The PBIQ-R subscale scores were then explored as potential mediators between attachment anxiety and emotional distress whilst controlling for PANSS symptom scores. Multiple mediation analyses showed that attachment anxiety exerted a significant indirect effect on emotional distress through the PBIQ-R subscales of shame and control (see Figure 2). When exploring the subscales of loss, entrapment, and social marginalisation were not found to mediate the relationship between attachment and distress. However it is important to note that this small sample size is likely to produce an overestimate in model variance. It is therefore recommended these results are viewed with caution until replication with a larger sample.

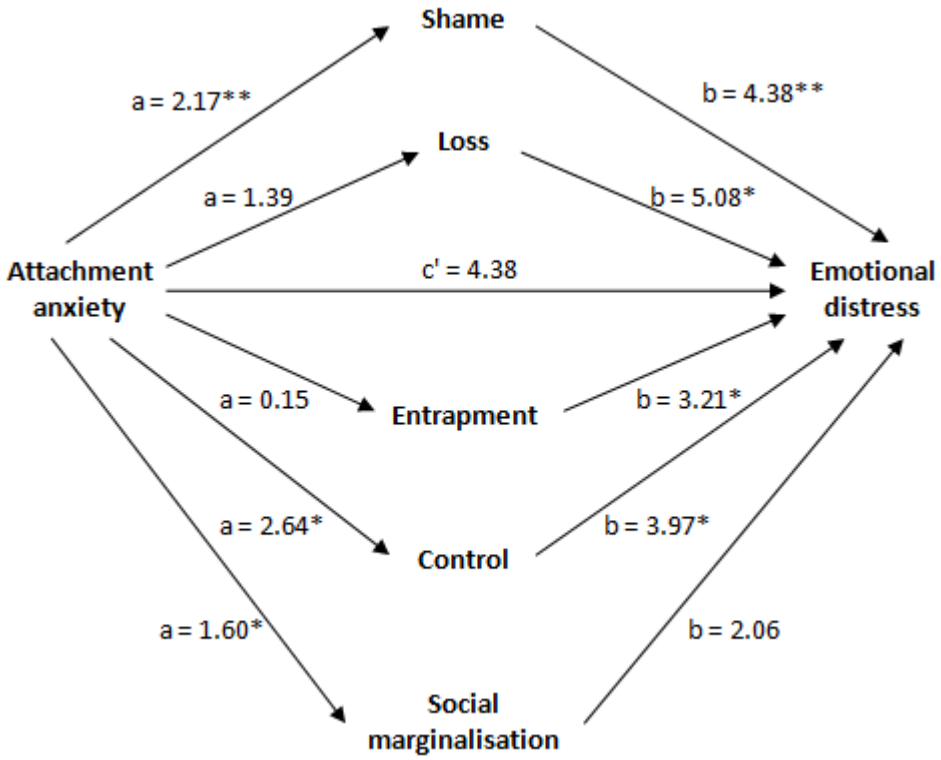

Figure 2. Results of exploratory analyses with PBIQ-R subscales of shame, loss, entrapment, control, and social marginalisation entered as mediators between attachment anxiety and emotional distress

Shame:

The 'a' path (attachment anxiety-shame) and the 'b' path (shame-emotional distress) were both found to be significant (a = 2.17, p=0.0041; b = 4.38, p=0.0089). A bias-corrected bootstrap confidence interval for the indirect effect (path 'ab' = 19.11, p=0.0038) did not contain zero (6.78-31.44). The direct effect of attachment anxiety on emotional distress (c' path) did not remain significant (c' = 9.61, p=0.1369). This model (including predictor variables) explained 28.97% of the variance in emotional distress.

Control:

The 'a' path (attachment anxiety-control) was found to be significant (a = 2.64, p=0.0015) but the 'b' path (control-emotional distress) was not (b = 0.72, p=0.6667). A bias-corrected bootstrap confidence interval for the indirect effect (path 'ab' = 19.11, p=0.0038) did not contain zero (6.78-31.44). The direct effect of attachment anxiety on emotional distress (c' path) did not remain significant (c' = 8.61, p=0.2001).

2.6 Discussion

The study aimed to explore the relationship between attachment, reflective functioning, cognitive appraisals, and emotional distress in people who experience psychosis. This first hypothesis was partially supported with attachment anxiety, cognitive appraisals of the self in relation to others, and emotional distress significantly related. The significant relationships found between these variables is supported by previous literature (Birchwood *et al*., 2006; Darrell-Berry, Bucci, Palmier-Claus, Drake, & Berry, 2017; Gumley, Taylor, Schwannauer, & MacBeth, 2014; Iqbal, Birchwood, Chadwick, & Trower, 2000).

However a relationship was not found between reflective functioning and either attachment anxiety or any measures of distress, and so hypothesis one was not fully supported. The lack of association found between reflective functioning and distress is surprising given that those with greater capacity

for reflective functioning are suggested to be better able to understand their own affective state (MacBeth, Gumley, Schwannauer, & Fisher, 2011). Findings from this study suggesting reduced capacity for reflective functioning is not associated with distress therefore appears to stand in contrast with previous research on reflective functioning in psychosis.

Whilst literature (eg Fonagy, Gergely, Jurist, & Target, 2002) suggests associations between attachment and reflective functioning, previous reporting upon this relationship in psychosis has highlighted inconsistencies. For example, research which organised attachment classifications categorically, found significant differences in reflective functioning for the insecure dismissing but not insecure preoccupied groups (MacBeth, Gumley, Schwannauer, & Fisher, 2011). From a dimensional approach, this finding suggests that significant differences in reflective functioning exist for people who express high attachment avoidance but not in those expressing high attachment anxiety. If reflective functioning develops within the context of secure attachment as Fonagy *et al.* (2016) propose, then a more consistent relationship between reflective functioning and the dimensions of both attachment anxiety and avoidance might be expected. It is also of note that whilst the RFQ8 was validated for use with clinical sample groups, it had not yet been utilised with people who experience psychosis and may not be as well suited to this clinical group.

The study found a stronger positive association between emotional distress and attachment anxiety than attachment avoidance. Although attachment avoidance was significantly associated with the composite variable of distress, this appears to be reflecting scores in generalised anxiety rather than across all three scales. Despite this, evidence suggests that attachment insecurity, whether high avoidance or high anxiety, is also associated with difficulties in regulating emotions (Mikulincer & Shaver, 2019). Findings may therefore reflect differences in emotion regulation strategies rather than emotional expression. This is consistent with the theory that those reporting

high attachment avoidance deactivate the attachment system and avoid emotional expression as others are perceived negatively (Carnelley, Otway, & Rowe, 2016).

Previous exploration of associations between attachment style and distress in psychosis reported both attachment anxiety and avoidance predicting anxiety and depression (MacBeth, Schwannauer, & Gumley, 2008). It is inconsistencies such as this in the evidence base that led Carnelley, Otway, and Rowe (2016) to explore relationships between the dimensions of attachment (anxiety and avoidance) and mood (anxiety and depression). Through the use of an attachment priming design, Carnelley, Otway, and Rowe (2016) concluded that whilst attachment insecurity in general is associated with emotional distress, the relationship between anxiety and depression with attachment anxiety is perhaps more reliable.

No significant relationship was observed between PANSS symptom severity and emotional distress. This finding is surprising as the association between anxiety and depression with severity of psychotic symptomatology has been observed through systematic review (Hartley, Barrowclough, & Haddock, 2013). This result may be linked to the previously mentioned clinical characteristics of the sample group where symptom scores lay below clinical cut off values. Findings may also reflect the small sample size which varied widely in current PANSS symptom severity due to being drawn from community, rehab, and acute settings. Whilst a chronic population drawn from community settings may not be symptomatic and are thus not a group who are high in expressed emotion, those participants from acute settings may present with a different symptom and emotion profile. The stage of illness and phase of disorder is therefore an important issue which future studies may attend to in further detail. Although limitations in sample size mean it is necessary to draw only tentative conclusions, this study appears to support Birchwood's (2003) proposed theory of three overlapping pathways

to distress in psychosis rather than a singular pathway of distress being intrinsic to psychosis.

The second hypothesis was also partially supported. Reflective functioning was not further explored as a potential mediator due to lack of association with the other key variables of attachment anxiety and distress. Nevertheless, cognitive appraisals (PBIQ-R) mediated the relationship between attachment anxiety and emotional distress. This provides further support for the use of SMT in explaining one of Birchwood's (2003) three pathways to distress. Receiving a stigmatising diagnosis may represent a 'threat' and subsequent negative evaluation of one's own social ranking in comparison to others after experiencing psychosis may lead to increased emotional distress.

Findings suggest that greater negativity in PBIQ-R scores increases the level of distress, particularly for those with greater attachment anxiety. The mediation model highlights cognitive appraisals such as perceptions of shame and loss of control as potential influential factors in emotional distress for people who experience psychosis. These findings might also help to explain the variation in emotional distress experienced by those who have greater levels of attachment anxiety.

2.6.1 Clinical Implications

This study has clinical implications as findings suggest the importance of exploring self and other cognitive appraisals when working with service users who have experienced psychosis. The role of shame cognitions and recovery implications have recently been highlighted in literature for people who experience psychosis (Keen, George, Scragg, & Peters, 2017). Whilst the importance of attending to shame appraisals is also highlighted in this study's findings, the impact of appraisals about control may warrant further investigation.

Although controlled trials of interventions designed to target shame-based cognitions are increasingly being developed (e.g. Morrison *et al*., 2016; Wood, Byrne, Enache, & Morrison, 2018), primary outcomes have not focused upon measures of distress. This study provides tentative evidence for exploring the potential of cognitive interventions targeting shame and control based cognitions when working to reduce emotional distress. It is hoped that greater understanding of key cognitions influencing emotional distress for people with psychosis will enable researchers to refine their interventions in the future. Furthermore, researchers developing interventions may seek to further investigate emotional distress as a key outcome.

2.6.2 Limitations of the study

This study encountered a number of limitations. Firstly, recruitment was reliant upon referrals from care co-ordinators/keyworkers, and clinicians may have been reluctant to approach service users who they perceived as unlikely to participate or more unwell despite capacity to consent to research. This 'screening' of potential participants may have led to sampling bias. Additional confounding variables such as neurocognition may have been present. Evidence suggests there is an association between neurocognitive impairments (e.g. in the domains of abstraction, memory, and attention) and negative appraisals about the self such as defeatist beliefs (Grant & Beck, 2008). Whilst the average age of study participants was 44, the average age of onset was 25 with some participants reporting symptom onset age 16. The possible long-term exposure to antipsychotic medication means that there is potential for this to exert a negative effect upon cognitive functioning (Husa *et al.,* 2017). This factor may therefore have influenced PBIQ-R scores as a confounding variable in the study.

The study was also limited by the small sample size. As previously noted, it is possible that small sample size led to findings such as lack of association between psychotic symptomatology and distress. Although steps such as bootstrapping of data were taken in a attempt to mitigate this issue, it is

recognised that a larger sample size would reduce the risk of Type II errors, especially given the potential range of illness stages. Future studies with larger sample sizes may further investigate cognitive appraisals with greater appreciation of different illness stages. Finally, the study did not account for differences in emotional regulation as a potential confounding variable when measuring expression of emotional distress. It is therefore recommended that future studies explore difficulties in emotion regulation and control for this potential confounding variable if required.

2.6.3 Conclusions

This study explored the relationship between self and social knowledge and emotional distress in psychosis. It identifies a pathway from attachment anxiety to distress through personal beliefs about illness. Greater negativity in personal beliefs about illness may lead to increased expression of emotional distress. It is hoped that future research will continue to explore the factors influencing the levels of emotional distress experienced by people with psychosis whilst developing increasingly efficacious interventions to support people in their recovery throughout the course of illness.

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Appendix A Clinical Psychology Review Author Guidelines

Declaration of interest

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential competing interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors must disclose any interests in two places: 1. A summary declaration of interest statement in the title page file (if double-blind) or the manuscript file (if single-blind). If there are no interests to declare then please state this: 'Declarations of interest: none'. This summary statement will be ultimately published if the article is accepted. 2. Detailed disclosures as part of a separate Declaration of Interest form, which forms part of the journal's official records. It is important for potential interests to be declared in both places and that the information matches. More information.

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Sections

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- Abstract;
- Keywords;
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- Acknowledgments.

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Bradley-Johnson, S. (1994). *Psychoeducational assessment of students who are visually impaired or blind: Infancy through high school* (2nd ed.). Austin, TX: Pro-ed.

Internet Document

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Author Guidelines updated 10th April 2019

Appendix C Non-CTIMP Study Protocol

Attachment, Information Processing, and Distress in Psychosis

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CONTENTS

LIST OF ABBREVIATIONS

ACCORD	Academic and Clinical Central Office for Research & Development - Joint office for The University of Edinburgh and Lothian Health Board
AE	Adverse Event
AR	Adverse Reaction
BCSS	Brief Core Schema Scale
CDSS	Calgary Depression Scale for Schizophrenia
CI	Chief Investigator
CMHT	Community Mental Health Team
CPN	Community Psychiatric Nurse
CRF	Case Report Form
DSM	Diagnostic and Statistical Manual of Mental Disorders
GAD-7	Generalised Anxiety Disorder 7-Item Scale
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
NHS	National Health Service
NICE	National Institute of Clinical Excellence
PAM	Psychosis Attachment Measure
PANSS	Positive and Negative Symptom Scale
PBIQ-R	Personal Beliefs about Illness Questionnaire - Revised
PI	Principal Investigator
QA	Quality Assurance
R&D	Research & Development Office

REC	Research Ethics Committee
RFQ	Reflective Functioning Questionnaire
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SIAS	Social Interaction Anxiety Scale
SOP	Standard Operating Procedure

INTRODUCTION

The term 'psychosis' relates to a number of conditions which are characterized by alterations in a person's perceptions, thoughts, mood, and behaviour (NICE, 2004). During these alterations, positive and negative symptoms will occur in a combination unique to each individual (Kay, Opler, & Lindenmayer, 1988). Significant levels of stigma around psychosis continues to exist in society, with 87% of respondents to a recent report disclosing direct experience (Schizophrenia Commission, 2012). Research investigating the impact of these social experiences has indicated that stigmatizing social encounters may influence both the behaviour a person exhibits and the beliefs they hold (Mestdagh & Hansen, 2014). As such, it is necessary to give further consideration to the social and relational aspects of people's lives.

When considering the social and relational aspects of people's lives it is possible to break these interactions down into two parts - the 'self' and the 'other'. This is as an individual will be making attempts to interpret information so as to understand not only their own thoughts, feelings, and behaviours, but also of others within any given environment. Such attempts to interpret social information have led us to develop a number of strategies or processes. Although these processes allow people to make sense of how they think or feel about themselves and other people, they also allow for comparison. The comparative element of our cognitive processes provides an opportunity for people to understand themselves in relation to others. Effective processing of social information may be considered advantageous as accurate appraisals are suggested to serve a vital role in managing threat, specifically the potential threat of becoming socially rejected thus losing control over access to resources (Trower & Gilbert, 1989). Research has found that many people with psychosis associate their illness status with high levels of shame, blame, and fear of discrimination (Corrigan & Watson, 2002;

Brohan et al, 2010). As psychosis is a highly stigmatized diagnosis in society, it is important to investigate the ways in which information about themselves and other people is being processed. Greater clarity about the ways this information is being processed may advance our understanding of the impact it holds the potential to exert upon developmental pathways to distress.

Psychosis and Psychological Distress

People with psychosis commonly experience emotional disorders such as anxiety and depression, with the high prevalence of such comorbidities increasingly recognised within literature (Buckley, Miller, Lehrer, & Castle, 2009). This study seeks to build upon the evidence base which has frequently taken generalised anxiety and depression as measures of distress. More recently, research has highlighted the role of shame in hampering emotional recovery from psychosis due to the strong association between shame and depression in this population (Keen et al., 2017). Research has also shown that the social anxiety experienced by a number of people with psychosis is associated with an internalisation of negative stereotypes (Pallanti et al., 2004). A more nuanced approach to emotional distress will be followed within this study, and include measures of shame and social anxiety alongside generalised anxiety and depression.

Hartley, Barrowclough, and Haddock (2013) comment on the Diagnostic and Statistical Manual of Mental Disorders (DSM) system, which is used by many in research within this area of interest. They (Hartley, Barrowclough, & Haddock, 2013) state that exclusion rules mean that emotional concerns are assimilated and the schizophrenia spectrum disorder takes primacy. Debate exists within the literature as to the extent of overlap between emotional disorder and symptomatology, with some suggesting for example that depression may be an intrinsic part of schizophrenia (Siris, 2004). There is therefore potential for a diagnosis of psychosis to overshadow an emotional disorder (Hartley, Barrowclough, & Haddock, 2013), and so the importance of exploring distress is highlighted.

Distress and Cognitive Models in Psychosis

Birchwood (2003) argues for the existence of three overlapping pathways to distress experienced as, for example, anxiety or depression in psychosis. The first pathway of emotional disorder and thus distress is described as intrinsic to psychosis. The second pathway reflects evidence that developmental trauma and social difficulties can act as risk factors for emotional disorder in psychosis (Bak et al., 2005). This is as cognitive schemas which blend experiences from the past and present influence information processing about the self and others (Beck, 1976). Therefore, a

schema may become active and either facilitate or disrupt adaptation to psychosis and its symptoms (Birchwood, 2003). For example, paranoid anxiety reinforced by a schema about the malevolent intent of others developed through experiences of childhood trauma may lead to greater levels of anxiety and avoidance coping.

A third pathway considers the possibility of emotional disorder as a reaction to psychosis. This pathway is concerned with how individuals appraise the personal threat of their diagnosis of psychosis, by perceived shame due to stigma and changes in social rank (Birchwood, 2003). Birchwood et al. (2006) comment that receiving a diagnosis of psychosis may be experienced as a challenge, further than the challenge presented by symptoms, to an individual's identity due to issues of stigma and social desirability. This is consistent with the views of Morrison (2001) who emphasised that beliefs about cultural acceptability can shape the appraisals people make about their anomalous experiences. A diagnosis of psychosis may reinforce an individual's beliefs that their experiences are not culturally acceptable thus prompting reappraisal of social desirability. Distress experienced in the form of depression was noted by Iqbal, Birchwood, Chadwick and Trower (2000) in participants who held cognitive appraisals that their diagnosis of psychosis had enforced a lower social status. A psychological model of post psychotic depression suggests a cognitive process of regained insight might change illness appraisals and therefore the impact of diagnosis itself (Birchwood et al 2005). However Gilbert (2000) argues that emotional expressions of distress such as shame, anxiety and depression might be conceptualised as submissive strategies when individuals find themselves in position of unwanted low status/social rank positions. This may mean that the emotional impact of diagnosis does not change with additional insight until the unwanted social ranking position is cognitively reappraised.

The Impact of Attachment

Attachment is described by Mikulincer, Shaver, and Pereg (2003) as one of the most important conceptual frameworks for understanding how an individual regulates their emotions when managing threat. As a result of interactions with caregivers during infancy and childhood, individuals develop mental representations of both the self in relation to others, and how others are expected to behave in social relationships (Bowlby, 1969). The attachment system functions to monitor and appraise potentially threatening events before activating mental representations of strategies to facilitate security with the aim of coping with any distress that arises from the threat (Mikulincer, Shaver, & Pereg, 2003). These mental representations are hypothesised to become working models which guide an individual's

attention, interpretations, and predictions about themselves and others within the social environment (Waters & Waters, 2006).

It has been argued that there are clear overlaps between the constructs of self and other schemata in cognitive models of psychosis and Bowlby's working models, albeit with the caveat that working models are influenced to a greater extent by affective experiences (Berry, Barrowclough, & Wearden, 2007). A relationship between internal working models and social rank may be noted through the internalisation of secure attachment where others are regarded safe/helpful/supportive, as this means safeness is activated socially. Conversely, those with insecure attachment may find social rank to be a source of threat, and due to their increased focus upon threat, an attentional bias towards issues of social rank may be observed (Laithwaite et al., 2009). If an individual perceives their diagnosis of psychosis as a threat, the attachment system will be activated and their individual working models might be expected to guide that person's attention, interpretations, and predictions about the themselves and others. Attachment theory might therefore be considered as a useful framework for understanding a person's adaptation to the experience of psychosis.

Overall, a review of the literature has demonstrated that the processes underlying the development of distress as they relate to the adaptations people make to a diagnosis of psychosis and subsequent evaluations about their social environment remain unclear. If the distress a person with psychosis experiences as a result of stigma differs according to how they are processing information, this may have implications for the way services understand and treat such distress. The proposed study will further explore attachment, self and other processing, and distress in psychosis in the hope of further clarifying the relationship between each of these components.

STUDY OBJECTIVES

Primary Objective

This study aims to explore the relationship between the patterns of how people relate to other people in order to have their needs met (attachment), the thoughts and feelings people use about themselves and others to make sense of social situations, and distress in people who experience psychosis.

Secondary Objectives

Does the way people who experience psychosis think about themselves and other people influence the relationship between attachment and distress?

Does the ability to think about and reflect upon their thoughts influence the relationship between attachment and distress for people who experience psychosis?

OUTCOME MEASURES

Primary Outcome Measure

The primary outcome is distress as measured by the Generalised Anxiety Disorder Scale, Social Interaction Anxiety Scale, and Calgary Depression Scale for Schizophrenia.

Secondary Outcome Measures

Secondary outcome measures for this study are putative mediators. They include the Personal Beliefs about Illness Questionnaire – Revised (PBIQ-R; Birchwood, Jackson, Brunet, Holden, & Barton, 2012) and the Reflective Functioning Questionnaire (RFQ; Fonagy et al., 2016). The extent to which these outcomes exerts influence over the relationship between attachment and distress will be tested.

STUDY DESIGN

This is a cross-sectional study that is expected to last for 1 year and 5 months. A sample of 54 adults over the age of 16 with a diagnosis related to the symptoms of psychosis as determined by the treating clinician will be recruited to the study. This sample group will be drawn from the 3 NHS Forth Valley localities of Falkirk, Stirling, and Clackmannanshire. Individuals who meet the study inclusion criteria within those localities will be identified and offered the opportunity to participate by completing a pack of questionnaires and a semi-structured interview with the researcher. Information during interviews will be collected by means of standardised questionnaires regarding psychotic symptomatology, attachment, distress, cognitive appraisals, and reflective functioning. Those who can consent independently will be included in the sample.

It is anticipated that participants will be in the study for a maximum of 1 month. This accounts for the length of time it may take from participants giving verbal consent after being initially approached by their clinician to the scheduling of an appointment for completion of written consent and study measures. It also accounts for any time taken through the rescheduling of

meetings or the scheduling of a second meeting to complete study measures where appropriate, including at the request of participants.

Three recruitment pathways will be used to identify potential participants from within secondary care services in NHS Forth Valley. The first recruitment pathway is via the Integrated Community Mental Health Services and will involve members of the multi-disciplinary team. The second recruitment pathway is via in-patient units and the Community Rehabilitation Team where members of the relevant multi-disciplinary team will be involved. In each recruitment pathway, clinicians will be contacted and provided with an information sheet about the study and asked to identify individuals on their current caseload who may meet inclusion criteria. Clinicians will then discuss the opportunity to participate in this research study with those individuals identified, and provide them with a participant information sheet. A self-referral pathway will be available for individuals who attend clinics where posters advertising the study will be displayed on notice boards in NHS clinic waiting areas. The poster will provide a clear process for self-referral and ask those who are interested to contact their keyworker, who will know about the study and be able to provide additional information. Any keyworkers who receive a request from their client will discuss their wish to be included in the study will gather verbal consent from the client to follow this up with the registered clinician. The clinician will then be able to check the self-referred client meets inclusion criteria and provide a participant information sheet where appropriate.

The clinician will then check back, at least 24 hours after potential participants have been provided with the participant information sheet, to ask whether the potential participant would like to participate in the study and give verbal consent for their contact details to be given to the researcher. Following this, potential participants will be contacted by the researcher to discuss what the study will involve and will be given at least 24 hours to consider whether they wish to participate. Participation will be voluntary, and all participants will continue their usual psychological, psychiatric and medical care during the study. Once a potential participant gives verbal consent to participate, the researcher will then liaise closely with the clinical team to discuss any relevant issues to their participation in the study. The participant will be invited to a one-off meeting that will be scheduled at a mutually agreed time/location such as in NHS locality clinic or home visit, with consideration of risk information, and adhere to local NHS lone-working policy. Participants will be informed during prior contact and information about the study that this meeting will last approximately 90 minutes but will include written consent, the questionnaire pack, and the semi-structured interview. Although this time is inclusive of breaks, participants may wish

instead to complete the questionnaire pack and semi-structured interview in two separate meetings of 40 minutes each; this will be facilitated by mutual agreement where appropriate. The clinician will be present during the completion of study measures and interviews will be audio-recorded for the purposes of ensuring coding accuracy.

STUDY POPULATION

NUMBER OF PARTICIPANTS

A total of 54 adults with a diagnosis related to the symptoms of psychosis as determined by the treating clinician will be recruited to the study. The main recruitment window is over a period of 10 months from January to October 2018.

INCLUSION CRITERIA

1) Individuals who are currently in contact with NHS mental health services

2) Individuals who have a diagnosis related to the symptoms of psychosis as determined by the treating clinician

3) Individuals aged 16+ who are willing to participate voluntarily and able to give written informed consent

4) Individuals who have sufficient understanding of English to complete the measures.

EXCLUSION CRITERIA

1) Individuals not currently in contact with NHS mental health services

2) Individuals with a history of organic factors implicated in the aetiology of psychotic symptoms e.g. brain injury

3) Individuals who currently lack capacity to consent to research

4) Individuals who have a level of understanding English which prevents completion of questionnaires

PARTICIPANT SELECTION AND ENROLMENT

IDENTIFYING PARTICIPANTS

Clinicians will be contacted to discuss and identify individuals on their current caseload who may meet inclusion criteria. A self-referral pathway will be available for individuals who attend clinics where posters advertising the study will be displayed on notice boards in NHS clinic waiting areas. The

poster will provide a clear process for self-referral and ask those who are interested to contact their keyworker, who will know about the study and be able to provide additional information.

CONSENTING PARTICIPANTS

Potential participants will be provided with the Participant Information Sheet about the study, and will be given at least 24 hours to consider whether they wish to participate. Clinicians will not discuss personal or identifiable information with the researcher before potential participants have expressed an interest in taking part.

Once a potential participant has given verbal consent to their clinician, the researcher will then discuss current presentation, issues pertaining to risk, potential for distress through engaging with this research, and capacity to consent with the clinician on an individual case-level basis. Those who agree to participate will meet with the researcher who will give potential participants the opportunity to ask any questions about the study and confirm inclusion criteria. A written consent form will then be completed by participants.

Withdrawal of Study Participants

Participants are free to withdraw from the study at any point or a participant can be withdrawn by the Investigator. If withdrawal occurs, the primary reason for withdrawal will be documented in the participant's case report form, if possible. The participant will have the option of withdrawal from:

(i) all aspects of the trial but continued use of data collected up to that point

(ii) all aspects of the trial with removal of all previously collected data.

All participants will be informed of their right to withdraw from the study at any stage they wish during the consent process. Should a participant become distressed during the completion of measures, they will be reminded of this right to withdraw.

The researcher is a Trainee Clinical Psychologist and has observational experience of assessing capacity. If through discussions with the participant about the study prior to consent the researcher holds concerns about the participant's capacity to provide informed consent, the researcher will thank participants for their interest, advise that they do not meet inclusion criteria for the study, and contact details for the potential participant shall be destroyed.

If a participant who has given informed consent loses capacity to consent during the study, the participant and all identifiable data collected would be withdrawn from the study. Data which is not identifiable to the research team may be retained.

STUDY ASSESSMENTS

The questionnaire pack and semi-structured interview will be administered during a single meeting with the researcher unless a further appointment is requested by the participant and mutually agreed as appropriate.

Demographic Data

Relevant demographic data will be collected during the participant interview including; age, gender, relationship status, current medication, psychosis age of onset, and current psychiatric diagnosis/diagnoses.

Psychosis Attachment Measure

The Psychosis Attachment Measure (PAM; Berry, Wearden, Barrowclough, & Liversidge, 2006) is based on existing measures of attachment along the axes of anxiety and avoidance proposed by Bartholomew and Horowitz (1991) so as to reveal working models of the self and others. The PAM was adapted to reduce the strong emphasis on romantic relationships thus improving relevance to individuals with psychosis whose opportunities for such relationships may be significantly reduced. The self-report version of the PAM has 16 items, with participants asked to rate each item using a 4-point scale ranging from ‘not at all’ to ‘very much’. The PAM is suggested to have good psychometric properties with acceptable levels of internal consistency reported (Cronbach’s alpha for the dimensions of anxiety 0.82 and avoidance 0.75) and concurrent validity in line with that demonstrated by other self-report measures of attachment (Berry et al., 2006).

The Personal Beliefs about Illness Questionnaire-Revised

The Personal Beliefs about Illness Questionnaire – Revised (PBIQ-R; Birchwood, Jackson, Brunet, Holden, & Barton, 2012) is a 20-item self-report measure designed to reflect current constructs of social rank theory in relation to people experiencing psychosis. These five constructs are named as; shame, loss, entrapment, control over illness, and social marginalization/group fit. The scales do not reveal a total score, but instead are designed to be subjected to individual analysis whilst supporting the

undelying theoretical contruct. The PBIQ-R was found to be internally consistent (Cronbach alpha values for all five subscales between 0.7 and 0.81) whilst being described as being reliable and satisfactory in both concurrent and discriminant validity (Birchwood et al., 2012).

The Brief Core Schema Scales

The Brief Core Schema Scale (BCSS; Fowler, et al., 2006) is a 24-item self-report questionnaire that assesses beliefs about the self and others firstly by indicating yes/no before using a 4-point scale from ‘believe it slightly’ to ‘believe it totally’ to indicate the strength of belief. Scores are obtained across four subscales; postive-self, positive-other, negative-self, negative-other. The BCSS was found to be internally consistent (Cronbach alpha values for all four subscales between 0.79 and 0.87), reliable, and satisfactory in validity during testing with a sample group of people with chronic psychosis (Fowler et al., 2006).

The Reflective Functioning Questionnaire

The Reflective Functoning Questionnaire (RFQ; Fonagy et al., 2016) is an 8-item screening measure of reflective functioning. Each item of the measure provides a statement such as "I always know what I feel" to which participants are invited to respond using a 7-point scale from 'strongly disagreee' to 'strongly agree'. The RFQ is reported to hold satisfactory reliability and validity with across both clinical and non-clinical samples (Fonagy et al., 20016), however it is to be noted that this specific measure has not yet been used within psychosis research.

The Generalized Anxiety Disorder 7-Item Scale

The Generalized Anxiety Disorder Scale (GAD-7; Spitzer, Kroenke, Williams, & Lowe, 2006) is a 7-item self-report screening measure designed as a diagnostic and to assess symptom severity. Participants are invited to respond indicating how often they have been bothered by each of the seven itemised problems across four rating points from 'not at all' to 'nearly every day'. The GAD-7 is reported to posess excellent internal consistency Cronbach alpha = .92) alongside good reliability and validity (Spitzer, Kroenke, Williams, & Lowe, 2006).

The Social Interaction Anxiety Scale

The Social Interaction Anxiety Scale (SIAS; Mattick & Clarke, 1998) is a self-report questionnaire designed to assess generalised fears of social interaction. Participants are invited to “indicate the degree to which you feel the statement is characteristic or true about you” over a scale of 19 items

across five rating points from ‘not at all’ to ‘extremely’. High levels of reliability and validity were reported (Mattick & Clarke, 1998). The scale has been used frequently within research and notably by Gilbert (2000) who found social anxiety as measured by the SIAS to be strongly positively correlated with shame (0.58, p= <0.01) and depression (0.60, p= <0.01) within a clinical population.

Approximate time to complete questionnaire pack: 40 minutes.

Calgary Depression Scale for Schizophrenia

The Calgary Depression Scale for Schizophrenia (CDSS; Addington, Addington, & Schissel, 1990) is a 9-item structured interview which is regularly used within research and has good psychometric properties including internal consistency (Cronbach alpha value of 0.75) and both convergent and discriminant validity. The CDSS has been described as useful for research with psychosis sample groups as it ensures separation from negative and extra pyramidal symptoms (Upthegrove et al., 2010).

Positive and Negative Syndrome Scale

The Positive and Negative Syndrome Scale (PANSS; Kay, Fiszbein, & Opfer, 1987) is a 30-item interview-based instrument which is designed to provide a balanced representation of both positive and negative psychotic symptoms whilst gauging their relationship to each other. The interviewer rates each of the 30 items across a 7-point scale ranging from 'absent' to 'extreme'. The PANSS has been found to posess good psychometric properties, with support lent to the assertion that positive and negative scales are inversely intercorrelated once shared association with general psychopathology had been accounted for (Kay, Opler, & Lindenmayer, 1988).

Approximate time to complete semi-structured interview: 40 minutes

DATA COLLECTION

Data will be collected during a one-off scheduled appointment with the researcher using the standardised measures noted above in Section 6, Study Assessments. The questionnaire pack and semi-structured interview will be administered by the researcher, Hannah Buckland, Trainee Clinical Psychologist.

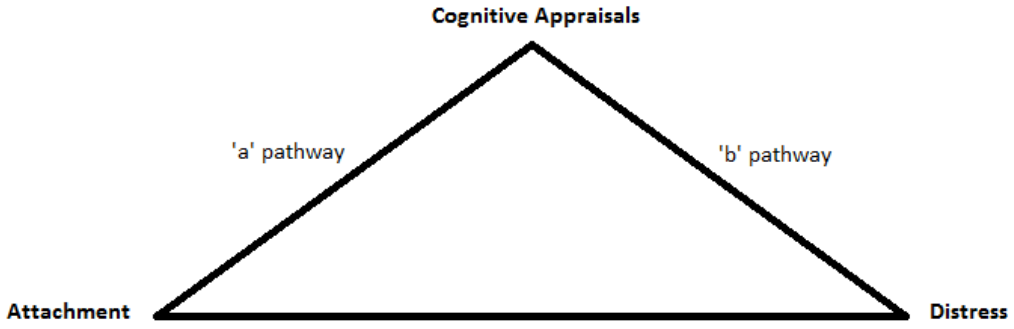
There is no requirement for the PANSS and CDSS to be audio-recorded during administration of the semi-structured interview. However in this study,

audio recording will take place to ensure accuracy of coding symptom responses.

STATISTICS AND DATA ANALYSIS

SAMPLE SIZE CALCULATION

Sample size was calculated according to guidance within Fritz and MacKinnon's (2007) article on planning to test mediated effects. Mediation model pathways within this calculation were based upon the research question, *'Do cognitive appraisals about illness mediate the relationship between attachment and distress in people who experience psychosis?'* with effect size estimates of 'a' and 'b' pathways drawn from previous research.

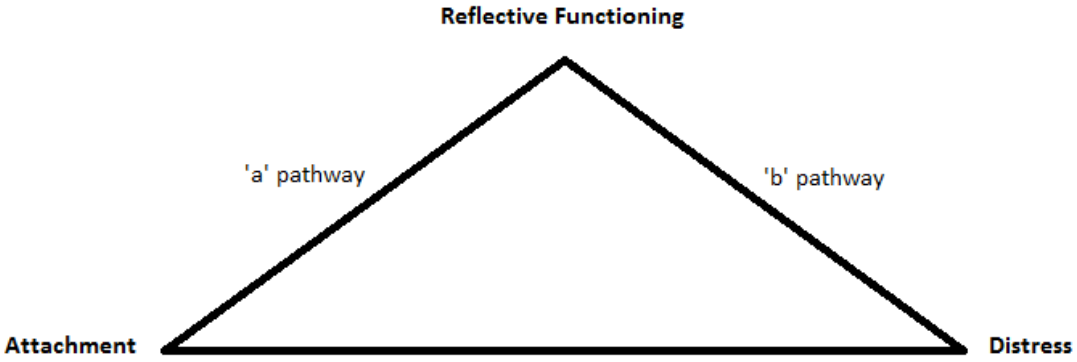


To calculate the sample size required to achieve 0.8 power whilst detecting small, medium, and large effect sizes in the proposed study the 'a' pathway is the relationship between attachment and cognitive appraisal, and the 'b' pathway is the relationship between cognitive appraisal and distress.

A number of studies have reported large effect sizes when exploring the relationship between attachment and cognitive appraisal (e.g. Rowe & Carnelley, 2003; Collins & Feeney, 2004; Sheinbaum et al., 2015). Whilst this has not been fully explored in a clinical population with a diagnosis of psychosis, Mikulincer and Florian (1995) found associations between attachment and the appraisals adults made of a real-life stressful situation. Their (Mikulincer & Florian, 1995) exploration into threat based cognitive appraisals of a stressful situation is relevant to the proposed study as the conceptualisation of diagnosis with psychosis as a stressful situation and potential source of threat for a person. As described previously in section 3.4 it is the cognitive appraisal people make of their potentially threatening illness status that the PBIQ has been designed to measure. A large effect size was found by Michail and Birchwood (2013) when exploring the relationship

between the PBIQ and distress as operationalised by experiences of shame and anxiety in psychosis.

As this initial mediation model is not wholly based upon previous studies with a psychosis population, a second mediation model was explored. In this model the 'a' pathway is the relationship between attachment and reflective functioning, and the 'b' pathway is the relationship between reflective functioning and distress.



MacBeth et al. (2011) evaluated the relationship between attachment and reflective functioning in a first-episode psychosis sample group and reported large effects. Furthermore, Smith et al. (2006) reported moderate effect sizes when exploring the relationship between reflective functioning and distress as operationalised by experiences of depression and distress caused by auditory hallucinations in a sample group with a current diagnosis of non-affective psychosis.

Based upon these findings, Fritz and MacKinnon (2007) suggest that a sample size of 34 participants should be used as a lower limit for 0.8 power. If recruitment proves successful and a sample size of 54 is reached then this will allow greater possibility of detecting for the potentially smaller effect sizes in a psychosis sample group as seen within the 'b' pathway of the second model with 0.8 power.

These sample sizes are estimates when testing a simple mediation model using bias-corrected bootstrapping. Although bias-corrected bootstrapping can increase likelihood of Type I error, Fritz and MacKinnon (2007) note this method to be acceptible, and found a sample size of between 50-100 to be present within almost a quarter of literature surveyed for mediation testing.

A scoping exercise has been completed within NHS Forth Valley secondary care services with the assistance of psychiatry, Community Psychiatric Nurses (CPNs), and psychology to estimate the available sample size.

Clinical Psychologists working in each locality have stated their intention to support the recruitment of participants in that area. On discussing the proposed study within a Falkirk Community Mental Health Team (CMHT) multi-disciplinary meeting, the team and Consultant Psychiatrist felt that the lower limit of 34 participants could be found within that area alone. On meeting with CPNs from Clackmannanshire, it was estimated that each had a caseload of 8 people with psychosis, with between 3 and 5 of these people anticipated as likely to participate in the study. Similar figures from the Stirling area provide an estimated sample pool of 64 people and a likely yield of 24 participants minimum.

The opinion of clinical psychologists working within secondary care is that this population tend to be hard to access for research but that engagement, if measures can be completed in one sitting, is high. To maximise opportunities for access and thus engagement, a number of recruitment pathways have been outlined along with a marketing window.

PROPOSED ANALYSES

Data will be analysed using SPSS, with descriptive statistics explored through the calculation of mean (standard deviation) for continuous variables, and frequency percentages for categorical variables. All variables will be checked for normality using the Shapiro-Wilk test as despite possible concerns over its sensitivity in small sample sizes, it is widely regarded as the best test of normality and provides better power than the alternative Kolmogorov-Smirnov test (Ghasemi & Zahediasl, 2012). The outcome of this test for normality will inform the next steps of data analysis, as any assumptions about the distribution of data will need to be considered when selecting parametic or non-parametric tests.

The relationships between key variables (symptoms, attachment, reflective functioning, cognitive appraisals, distress) will be explored. Both informant and self-rated attachment data will be explored for relationships with sub-scale scores for the Personal Beliefs about Illness Questionnaire and Brief Core Schema Scale.

It is hypothesised that self-other processing such as cognitive appraisals of social rank and reflective functioning may be the mechanism by which attachment exerts influence upon distress. To test this hypothesis single

mediation models will be independently employed. The first mediation model will use attachment as the predictor variable, cognitive appraisal (each of the 5 PBIQ subscales in turn) as the mediator variable, and distress as the outcome variable. The second mediation model will use attachment as the predictor variable, reflective functioning as the mediator variable, and distress as the outcome variable. Data will be analysed using Hayes' (2013) PROCESS macro model 4 for SPSS which will allow for bias-corrected bootstrapping. Any post-hoc testing of mediators operating in parallel or serial, as may be the case with the two hypothesised mediators of cognitive appraisal and reflective function, will be exploratory with the intention of informing future studies due to the sample size constraints.

POSSIBLE RISKS

Consent related issues

It is important that potential participants have an understanding of what the study is about and what will be required of them. Potential participants will be provided with verbal and written information in the form of a participant information sheet. Individuals approached to participate in the study will be informed that participation in the study will not affect their care and management. They will also be informed of their rights: declining participation in the study, withdrawing from the study at any stage and making a complaint. In each recruitment pathway, clinicians will be contacted to discuss and identify individuals on their current caseload who may meet inclusion criteria. Clinicians will confirm at this stage that the potential participant is able to give informed consent. The clinician will then provide all identified individuals with a study information sheet and offer the opportunity to participate in the study. The clinician/keyworker will then be asked to acquire consent from potential participants to be contacted by the researcher to discuss the study and arrange an appointment to meet. Following this, participants will be informed by the research assistant about the aims of the study and will be given at least 24 hours to consider whether they wish to participate. An opportunity to ask questions prior to consent will be given to all participants. Only individuals who provide written consent will be included in the study. Before they sign consent, all participants will be given an opportunity to ask any questions about the study and they will be informed about their rights.

In acknowledgement of the complexities which exist in managing risks related to capacity to consent, additional safeguards are proposed. Firstly, only those deemed holding the capacity to provide written informed consent will be invited to participate by the researcher. Secondly, written consent and completion of measures will take place within same appointment.

Potential distress of participants

During the administration of the psychological measures, participants with psychosis will be asked about their attachment, cognitions, and subsequent psychological distress. There is a possibility that a participant becomes distressed during the completion of measures. However, the selected questionnaires are widely used in research and clinical practice and evidence suggests that completion of these measures is unlikely to result in distress. Whilst the possibility of distress exists, it is of note that this may not be directly related to participating within the study. In consideration of both these eventualities, the researcher will be present whilst participants complete the measures to monitor levels of distress, thus assisting with the management of clinical risk. The researcher will take care to discuss any concerns of risk to participants and early warning signs for distress. Participants will also be encouraged to discuss any upsetting issues with clinical staff who are involved in their routine care. Despite these researcher-led strategies to manage the risk of participant distress, it is important to consider the participant themselves as a partner in managing this risk. All participants will have capacity to provide informed consent and as such are autonomous individuals with the ability to make their own choices in the participation of this study. Participants will be made aware of the content of each questionnaire, and their right to withdraw from the study including during completing measures. They will therefore be considered able to decide whether to continue participating throughout their appointment when completing the questionnaire pack.

Risk management and confidentiality

The participant's right to confidentiality will be stated within the process of gathering informed consent. Time will be taken to discuss the boundaries of this and the occasions when the researcher would disclose information to the participant's care team. This explanation of confidentiality will be drawn from standard procedure and highlight the researcher's responsibility to share information if she becomes concerned that there is a risk of harm to either the participant themselves or to others. If the researcher becomes aware of a risk of harm to either the participant or others then this will be managed according to local NHS risk management policy and procedures whilst

liaising closely with the clinical team. Appointments will be made in adherence with NHS lone-working and health and safety policies so as to facilitate access to the clinical team.

Data protection

Hard copies of questionnaires will be stored in a locked cabinet within the psychology department and any transportation of completed participant questionnaires between NHS sites will take place using a locked briefcase as per NHS Forth Valley protocols. Anonymised data will be entered into an electronic database and stored in accordance with the NHS Forth Valley Information Management Policy. This is to ensure that access is limited only to those who need to access the information, whether this is paper or electronic data records. Non-identifiable data will be made available to the academic supervisor where necessary following guidance within the NHS Information Sharing Policy and adhering to Caldicott Principles. Following completion of the research, both paper copies and electronic data will be retained and subsequently disposed of according to University of Edinburgh and NHS Forth Valley Records Management Code of Practice. This is to ensure data is stored securely and destroyed appropriately.

OVERSIGHT ARRANGEMENTS

INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

RISK ASSESSMENT

1) Failure to receive ethical approval

It is anticipated that the NHS Research Ethics Committee may raise concerns around possible adverse outcomes to participants from the completion of questionnaires. All measures within the study have been chosen due to their routine use within research or clinical practice with individuals who experience psychosis. As participants are already receiving input from NHS health care services, it is likely that they will have prior experience of either these specific questionnaires or ones with a similar focus.

Informed consent will be sought before individuals participate in the study. The process of gaining informed consent will include detailing the types of questions participants will be asked whilst ensuring individuals are aware of their right to withdraw from participating at any time, including during the completion of study questionnaires. The researcher will be present at all times whilst participants complete the questionnaires and will therefore be available to support participants or address distress should any arise.

2) Failure to recruit sufficient sample size

There is a risk that sufficient participant numbers will not be recruited to the study.

A marketing window of 2 months is proposed as this allows for attendance at each of the team meetings to raise awareness about the study. The trainee and researcher has been visiting psychiatry and CMHT departments within each locality in NHS Forth Valley since the beginning of first year. It is hoped that this will enable positive relationships with staff and clinical teams to be developed before initiation of study marketing and data collection.

A recruitment window of 12 months, inclusive of the 2 month marketing window, has been identified which allows time for a recruitment rate of approximately 4 participants per month assuming a sample size of 54. Should recruitment not progress as hoped, a lower limit sample of 34 may be acceptable (please see section 4.1 for further details of lower limits as related to individual mediation models), thus leading to a recruitment rate of approximately 3 participants per month over 12 months.

A number of recruitment pathways are proposed so as to encourage engagement from individuals with psychosis who access services in a variety of ways. Few recent research projects have recruited people with psychosis in NHS Forth Valley and so there is a reduced risk of competition from other projects and increased opportunity for accessing participants whose views have not already been sought. It is hoped that sufficient numbers will be recruited from within NHS Forth Valley, however through early discussion it is notable that a multi-site ethics application is supported should this risk need further mitigation.

3) Reliance on others to access potential participants

The study involves some reliance on clinicians to identify potential participants on their current caseload and feed this information back to the researcher. To reduce the risk of communication breaking down leading to an

insufficient sample size being recruited, time has been spent (see above) to ensure the researcher is known to clinicians so that positive working relationships can be developed and maintained.

Furthermore, a self-referral recruitment pathway is proposed to reduce the researcher's reliance on others to achieve the full sample size.

STUDY MONITORING AND AUDIT

The Research Governance and QA office (University of Edinburgh) will review the study and determine if an independent risk assessment will be performed by an ACCORD Clinical Trials Monitor to decide (a) if monitoring is required and (b) if so, at what level. An independent risk assessment may also be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before, during and/or after the study and if so, at what locations and at what frequency.

The researcher will meet with the academic supervisor once a month for the duration of the project to monitor recruitment in relation to targets; deal with any adverse events; and coordinate the different stages of the project from recruitment to analysis and dissemination of results. The researcher will update the clinical supervisor about progress on a monthly basis following academic supervision meetings, and meet to discuss clinical issues relating to the project when appropriate. Collaborative discussion between the supervisory team and the researcher will take place by telephone conferencing and email contact. Day-to-day project management including administrative issues, troubleshooting and recruitment flow will be the responsibility of Hannah Buckland (researcher and trainee clinical psychologist).

GOOD CLINICAL PRACTICE

ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

Informed Consent

In recognition of differences in the capacity people with psychosis have to provide fully informed consent, the registered clinician will consider their caseload and approach potential participants according to their clinical assessment of capacity. Clinicians will confirm that potential participants meet study inclusion criteria and have the capacity to provide informed consent. When initially approached by a clinician from their direct care team about their interest in the study, potential participants will be provided with the Participant Information Sheet for the study. This will detail what is involved in participating in the study. Individuals approached to participate in the study will be informed that participation in the study will not affect their care and management. They will also be informed of their rights: declining participation in the study, withdrawing from the study at any stage and making a complaint.

The clinician/keyworker will then be asked to acquire verbal consent from potential participants to be contacted by the researcher to discuss the study and arrange an appointment to meet. There will be a minimum of 24 hours between potential participants providing consent for clinicians to share their contact details and meeting the researcher to gather written consent. Following this, participants will be informed by the researcher about the aims of the study and will be given at least 24 hours to consider whether they wish to participate.

At this meeting, potential participants will have details of the study fully clarified and will have the opportunity to ask any questions. The researcher is a Trainee Clinical Psychologist and has observational experience of assessing capacity. If through discussions with the participant the researcher holds concerns about the participant's capacity to provide informed consent, the researcher will thank participants for their interest, advise that they do not meet inclusion criteria for the study, and contact details for the potential participant shall be destroyed.

After having the opportunity to ask any questions, potential participants will be asked to indicate whether or not they wish to participate in the study. If they wish to participate in the study, they will be asked to sign a consent form. It will again be made clear by the researcher that the potential participant can take more time to consider whether they wish to participate. It will also be made clear that participation is voluntary and neither their participation or non participation will affect their treatment as usual (whatever they receive as part of normal routine care). Only individuals who provide written consent will be included in the study.

Participants will receive both oral and written information when discussing their potential participation in the study. Appropriate Participant Information and Informed Consent Forms will be provided to support this discussion with the researcher. The researcher and the participant will sign and date the Informed Consent Form to confirm that consent has been obtained. The original copy will be retained in the site file, one copy is to be retained in patient notes, and one copy is to be retained by the participant.

In acknowledgement of the complexities which exist in managing risks related to capacity to consent, additional safeguards are proposed. Firstly, only those deemed holding the capacity to provide written informed consent will be invited to participate by the researcher. Secondly, written consent and completion of measures will take place within the same appointment.

Study Site Staff

The Investigator must be familiar with the protocol and the study requirements. It is the Investigator’s responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their study related duties.

Data Recording

The Principal Investigator is responsible for the quality of the data recorded.

Confidentiality

The participant's right to confidentiality will be stated within the process of gathering informed consent. Time will be taken to discuss the boundaries of this and the occasions when the researcher would disclose information to the participant's care team. This explanation of confidentiality will be drawn from standard procedure and highlight the researcher's responsibility to share information if she becomes concerned that there is a risk of harm to either the participant themselves or to others. If the researcher becomes aware of a

risk of harm to either the participant or others then this will be managed according to local NHS risk management policy and procedures whilst liaising closely with the clinical team. Appointments will be made in adherence with NHS lone-working and health and safety policies so as to facilitate access to the clinical team.

Data Protection

The transfer of personal data such as address, postcode, or telephone number may take place between clinicians and the researcher via email following the identification of potential participants who have verbally consented to contact from the researcher. Personal data will only be provided to the researcher by clinicians following discussion with the potential participant and their verbal consent to receiving contact from the researcher by whichever method as appropriate. Personal data will then be stored on an electronic database in accordance with NHS Forth Valley Information Management policy and any email records deleted.

Personal data collected through the consent process will be stored separately in hard-copy form. Paper files will be kept in a locked cabinet in the Department of Clinical Psychology, Mayfield Building, Falkirk Community Hospital. Anonymised data will be entered into an electronic database and stored in accordance with the NHS Forth Valley Information Management Policy. This is to ensure that access is limited only to those who need to access the information, whether this is paper or electronic data records. Non-identifiable data will be made available to the academic supervisor where necessary following guidance within the NHS Information Sharing Policy and adhering to Caldicott Principles.

The use of an audio recording device will be used during semi-structured interviews and may thus record personal data during the study. For the purposes of this study, an NHS encrypted audio recording device will be used and the NHS Forth Valley policy on use of such devices will be followed. The use of an audio recording device is not mandatory for the administration of the semi-structured interview, however data recorded will be used to check for accuracy of symptom recording and destroyed after coding of responses is recorded.

The study will adhere to the principles of Good Clinical Practice thus ensuring the confidentiality of personal data. Access to participant's personal data outwith the direct care team will be in accordance with NHS Information Sharing Policy. As such, the researcher will receive only the participant's name, contact telephone number and/or address, after participants have given permission for this to be provided. Storage of a password protected list

will follow NHS Information Management Policy and will be held separately on a restricted access area of NHS Forth Valley's server. Consent forms will comprise the link between a participant's name and their study ID number. As such, consent forms will be stored separately from all other data collected. Data collected through questionnaire and semi-structured interview will be labelled with the participant's ID code number. The electronic dataset will only hold anonymised data. The audio recording device will be NHS encrypted and interviews will be deleted after coding of responses is recorded. Any transportation of completed participant questionnaires and the audio recording device between NHS sites will take place using a locked briefcase as per NHS Forth Valley protocols.

STUDY CONDUCT RESPONSIBILITIES

PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator in collaboration with the supervisory team.

Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D for approval prior to participants being enrolled into an amended protocol.

MANAGEMENT OF PROTOCOL NON COMPLIANCE

Protocol deviations will be recorded in a protocol deviation log and will be reported to the sponsor within 3 days of becoming aware of the violation.

SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator or supervisory team, the co-sponsors (seriousbreach@accord.scot) will be notified within 24 hours. It will then be determined whether the incident constitutes a serious breach and report to research ethics committees as necessary.

STUDY RECORD RETENTION

All study documentation will be kept for a minimum of 3 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

Following completion of the research, both paper copies and electronic data will be retained and subsequently disposed of according to University of Edinburgh and NHS Forth Valley Records Management Code of Practice. This is to ensure data is stored securely and destroyed appropriately.

All paper copies of participant data will be stored in a locked cupboard within the Clinical Psychology Department at NHS Forth Valley. The box containing paper data will be clearly labelled as containing confidential data and a 10 year destroy date as per standard departmental practice to ensure data is stored securely and destroyed appropriately. The anonymised electronic dataset will be retained and held within the University of Edinburgh repository so as to adhere to the Scottish Executive Research Governance Framework (2006) and enable suitable archiving of data which may be later requested for checks. The Chief Investigator (Hannah Buckland) and Academic Supervisor (Dr Helen Griffiths) will be named as custodians for this archived data, as per the proposals agreed by the Joint Training Committee.

END OF STUDY

The end of study is defined as the last participant's last visit.

The Investigators or the co-sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, and R+D Office(s) and co-sponsors within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot.

A summary report of the study will be provided to the REC within 1 year of the end of the study.

INSURANCE AND INDEMNITY

The co-sponsors are responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the co-sponsors' responsibilities:

- The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.
- Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The co-sponsors require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.
- Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity.

REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

The study results will be reported and disseminated primarily through a portfolio thesis which will be submitted to fulfil the requirements of a Doctorate in Clinical Psychology at the University of Edinburgh. This document, once finalised, will be available through the Department of Clinical Psychology's Thesis Database to ensure open access for interested parties.

The overall results of this study (but not individual scores) will be presented to each of the clinical teams involved within the research. These findings will be disseminated back to NHS staff who were involved in the study through team meetings and an end-of-study newsletter. Participants will also be given the opportunity to request an overview of findings following study completion.

The systematic review and empirical study will be prepared for submission to peer-reviewed scientific journals such as Schizophrenia Research. The researcher will also identify and apply to present at relevant conferences following completion of the project.

AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team.

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Appendix D NHS Research Ethics Committee Favourable Opinion

07 March 2018

Ms Hannah Buckland
Trainee Clinical Psychologist
NHS Forth Valley
Department of Clinical Psychology
Falkirk Community Hospital
Mayfield Building, Major's Loan
FK1 5QE

Dear Ms Buckland

Study title:	**The mediating role of self and other information processing between attachment and distress in psychosis.**
REC reference:	**17/NW/0682**
Protocol number:	**CAHSS1710/05**
IRAS project ID:	**233753**

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Poster]	Version 1	02 November 2017
Copies of advertisement materials for research participants [Poster]	Version 2	03 January 2018
Copies of advertisement materials for research participants	Version 1	02 November 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
GP/consultant information sheets or letters [GP Letter]	Version 1	02 November 2017
Interview schedules or topic guides for participants [Combined PANSS and CDSS]	Version 1	02 November 2017
IRAS Application Form [IRAS_Form_13112017]		13 November 2017
IRAS Checklist XML [Checklist_03012018]		03 January 2018

Letters of invitation to participant [PIS for HCPs]	Version 1	02 November 2017
Letters of invitation to participant [Consent to Contact Form]	Version 1	03 January 2018
Non-validated questionnaire [Demographic Information Sheet]	Version 1	02 November 2017
Non-validated questionnaire [Demographic Information Sheet]	Version 2	03 January 2018
Non-validated questionnaire	Version 1	02 November 2017
Participant consent form [Consent Form]	Version 1	02 November 2017
Participant consent form [Consent Form]	Version 2	03 January 2018
Participant consent form	Version 1	02 November 2017
Participant information sheet (PIS) [PIS]	Version 1	02 November 2017
Participant information sheet (PIS)	Version 2	03 January 2018
Participant information sheet (PIS)	Version 1	02 November 2017
Research protocol or project proposal [Protocol v1 071117]	Version 1	07 November 2017
Summary CV for Chief Investigator (CI) [HB CV]		02 November 2017
Summary CV for supervisor (student research) [HG CV]		22 August 2017
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only)		
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only)		
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only)		
Validated questionnaire [General Anxiety Disorder 7-Item Scale]		
Validated questionnaire [Social Interaction Anxiety Scale]		
Validated questionnaire [Psychosis Attachment Measure]		
Validated questionnaire [Personal Beliefs about Illness Questionnaire - Revised]		
Validated questionnaire [Brief Core Schema Scale]		
Validated questionnaire [The Reflective Functioning Questionnaire]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

17/NW/0682	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

PP : Professor Carol Haigh
Chair

Email:nrescommittee.northwest-preston@nhs.net

Enclosures:	"After ethical review – guidance for researchers" *[SL-AR2]*
Copy to:	*Ms Charlotte Smith* *Dr Rosemary Wilson, NHS Forth Valley*